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Osteodistraction: Clinical applications in maxillofacial reconstructive surgery

PhD Dissertation

Arturo Bilbao Alonso

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D. Juan Manuel Seoane Lestón, Profesor Titular de la Facultad de Medicina y Odontología de la Universidad de Santiago de Compostela,

D. Pablo Ignacio Varela Centelles, Profesor Asociado de la Facultad de Medicina y Odontología de la Universidad de Santiago de Compostela

HACEN CONSTAR

Que el trabajo de investigación que presenta D. Arturo Bilbao Alonso, con el título de "**Osteodistraction: Clinical applications in maxillofacial reconstructive surgery**", ha sido realizado bajo nuestra dirección, supervisando en todo momento su elaboración.

Que a nuestro criterio reúne las características de rigor, originalidad y mérito suficientes para optar al grado de Doctor y ser elevado al superior juicio del Tribunal designado a tal efecto.

Para que así conste, a efectos de justificar los mencionados extremos ante los órganos competentes de la Universidad de Santiago de Compostela, firmamos a 13 de febrero de 2013.

Fdo. Juan Manuel Seoane Lestón

Fdo. Pablo Ignacio Varela Centelles

Fdo. Arturo Bilbao Alonso (doctorando)

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Introduction

1. Introduction

Current standards in implant dentistry aim to provide natural prosthetic restorations with the finest aesthetic and functional outcomes. Several parameters have been suggested in order to achieve gold-standard results: adequate bone height, width, anterior-posterior projection, adequate soft tissue quantity and quality, preservation of buccal sulcus, adequate papillae, and gingival contour. (Guerrero et al. 2007) Thus the preservation and reconstruction of the alveolar bone and surrounding soft tissues for the placement of dental implants has become one of the bases of the contemporary practice of oral and maxillofacial surgery, and multiple techniques have been utilized for these purposes.

Since its introduction in 1996, (Chin & Toth, 1996) alveolar distraction osteogenesis has been considered a viable technique for reconstruction of alveolar bone prior to implant placement. In 2004 the Oral and Maxillofacial Clinics of North America published an excellent article on alveolar distraction osteogenesis where Batal & Cottrell (2004) did a comprehensive review of the history, biological principles, devices, clinical applications and surgical techniques in alveolar distraction osteogenesis, which is strongly recommended for those interested in the basic concepts on alveolar distraction.

BIOLOGY OF ALVEOLAR DISTRACTION OSTEOGENESIS

Alveolar distraction osteogenesis uses the same biological principles described originally in the orthopaedic literature (Ilizarov, 1989): after performing an alveolar bone osteotomy, a distractor device is placed in the transport segment that remains fully vascularized via its periosteum. Subsequently the bony segment is subjected to gradual traction that separates it from the basal bone; this traction activates tissue growth and regeneration forming a distraction callus that progressively matures into bone. The resultant bone mass and shape depends on the vector of distraction, mechanical forces, and blood supply.

Several biological processes occur during and after distraction. In more recent years several publications have reported specifically on the biology of human alveolar distraction osteogenesis (Iizuka et al, 2005; Consolo et al, 2006; Chiapasco et al, 2006; Amir et al, 2006; Türker et al, 2007; Lindeboom et al, 2008; Chiapasco et al, 2006) and described that after 12 weeks of consolidation the percentage of mineralized bone formed in the distracted region ranged from 21.6% to 57.8%. The newly formed bone was oriented perpendicular to the osteotomy cut and consisted of woven bone reinforced by parallel-fibred bone. Türker et al (2007) reported similar histological findings after 12 weeks of consolidation and correlated these findings with panoramic radiographs, dental CT scans, and bone density analysis. Panoramic radiographs at the end of distraction showed radiolucent gaps, after 12 weeks the distraction gaps appeared mostly radio-opaque with some radiolucent areas, and after 1 year the appearances were the same as the pre-existing bone. Dental CT scans taken twelve weeks after distraction confirmed increase of alveolar heights and filling of the distraction chamber, after one year the CT scans showed formation of bone that appeared similar to pre-existing bone. Bone density analysis from the dental CT showed the newly formed bone after 12 weeks of consolidation was denser than medullary bone. Iizuka and colleagues (2005) demonstrated that a bidirectional alveolar distractor formed a high-density new bone with complex architecture. The new bone was oriented in several different layers. They concluded that the favourable bone regeneration was achieved due to the combination of slow distraction and gradual anterior angulation.

Consolo and colleagues (2006) compared the use of traditional alveolar distraction versus an intermittent loading alveolar distraction. After reaching the distraction goal the individual started an activation-deactivation protocol for 8 weeks during the consolidation phase. The histological results at 6, 8 and 12 weeks of consolidation showed evidence for early bone formation with superior structure quality

Adequate blood supply is crucial for the development, remodeling and regeneration of bone. Amir and colleagues (Amir et al, 2006) found a positive correlation between blood vessel volume and bone volume density in newly formed bone after alveolar distraction. This supports the concept that vascularity is necessary for the formation of new bone.

Lindeboom and colleagues (2008) reported on the vascular density changes in oral mucosa after alveolar distraction. They showed the main increase of vascularity was during the activation phase. The vessel density during consolidation was comparable to preoperative levels.

DISTRACTION PROTOCOL

After almost 15 years of widespread use, controversy still remains with regard to the best protocol to follow. As new devices and applications have been designed different distraction protocols have been tested and established. However the original clinical phases of distraction remain the same: osteotomy, latency, distraction and consolidation (Fig. 1).

Osteotomy

Traditionally the osteotomy has been done with rotary burs, different kinds of saws and osteotomes. Piezosurgery for alveolar distraction osteotomies has also been reported in the literature. (González-García et al, 2007; González-García et al, 2008) By comparing piezoelectric versus conventional osteotomies for alveolar distraction, González-García and colleagues (2008) found that the surgical difficulty and the incidence of intraoperative complications were significantly lower in the piezoelectric group. Their results showed that the post distraction alveolar morphology was worse in the piezoelectric group. They theorize that the piezoelectric osteotomies will create an initial wider gap that may favour the appearance of granulation tissue without good osteogenic potential.

Latency period

Latency period is defined as time from surgery to the beginning of distraction. In an alveolar distraction systematic review from 1996 to 2006, it was found that the most common latency period was 7 days (66% of the cases reviewed) to allow for healing of the mucoperiosteum and reduce the risk of wound dehiscence. Extended latency periods over 15 days were applied to ensure complete revascularization of the transport segment in cases where the mucoperiosteal pedicle is small or endangered (Saulacic et al, 2008).

Distraction period

The distraction period encompasses the time between initial activation and end of the activation of the distractor device. The amount of distraction required is generally based on the amount of tissue necessary to fulfill the implant and dental rehabilitation goals. Several studies have focused on the amount of alveolar distraction relapse and their recommendation is to overcorrect by 20% to 25% (Saulacic et al, 2005; Kanno et al, 2007). Apart from the amount of distraction needed, the distraction rate and rhythm are of paramount importance during this period.

Distraction rate

The daily amount of bone to be distracted is known as distraction rate. Saulacic and colleagues (2008) reported in a systematic review that the mean distraction rate was 0.71 ± 0.27 mm. They also noted a lower distraction rate of 0.4 to 0.5 mm in cases where distractor implants and horizontal distraction was used. According to Amir and colleagues (2006) a distraction rate of 0.5 mm a day results in faster osteogenesis than a distraction rate of 1mm in elderly patients.

Distraction rhythm

Distraction rhythm is the amount of distraction activations per day. According to Saulacic and colleagues (2008) the rhythm in alveolar distraction has tended to be chosen empirically in part to a lack of experimental findings. They reviewed 209 distractions in 197 patients, the rhythm of distraction ranged between one (62%), two (35%) and four times daily (3%).

Consolidation period

This is the period that allows for maturation and corticalization of the regenerated bone. According to Amir and colleagues (2006) a minimum of 10 weeks is required for new bone to bridge a 10mm alveolar distraction gap. It has been suggested that the poorly mineralized bone tissue found after 10 weeks of consolidation will start an adaptive response that would increase the bone matrix mineralization with placement of dental implants (Marchetti et al, 2007). A systematic review found that the mean consolidation period was 12.22 ± 5.58 weeks. A difference was noted in the consolidation period when different distractor devices were used. The mean consolidation period on intraosseous distractors was 8.82 ± 2.67 weeks, 11.44 ± 2.55 weeks for the extraosseous distractors, and 18.02 ± 3.50 weeks before prosthetic treatment started in distraction implants.

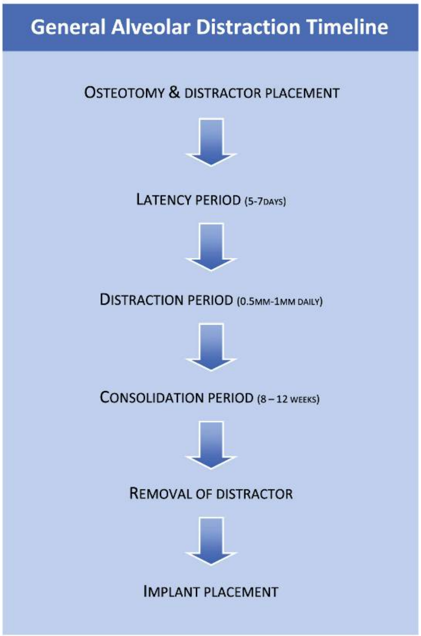

Fig. 1. General alveolar distraction timeline.

ALVEOLAR DISTRACTION DEVICES

Novel alveolar distraction designs are constantly being developed for research and clinical purposes. As a general rule they have been classified depending on the placement in relation to the bone as intraosseous and extraosseous. In a study comparing clinical outcomes of intraosseous and extraosseous alveolar distractors, Uckan and colleagues (2007), found no significant statistical difference despite the higher complication rate and lower implant success in the intraosseous group. Devices can also be categorized depending on the direction of the movement as unidirectional and multidirectional. Initial alveolar distractor designs allowed for only an unidirectional movement making correct positioning of the device and vector control most important. Recent publications have shown the clinical value of multidirectional alveolar distraction devices ((Iizuka et al, 2005; Robiony et al, 2004; Schleier, et al., 2007). In a retrospective study comparing outcomes of unidirectional and bidirectional distractor devices, Schleier and colleagues (2007) found no significant statistical differences in the bone gain or implant success. Moreover, several cases with unidirectional distraction had to be bone grafted at the time of implant placement. They concluded that this difference was due to the precise control of the distraction process in the bidirectional distraction group.

INDICATIONS FOR ALVEOLAR DISTRACTION OSTEOGENESIS

Several clinical indications for alveolar distraction osteogenesis have been reported in the literature (Nocini et al, 2004; Mendonça et al, 2008; Marcantonio et al, 2008) (Table 1). Alveolar reconstruction in preparation for dental implant placement continues to be the most common indication (Fig 2). Reconstruction efforts have used alveolar distraction as a definitive procedure to establish the ideal alveolar ridge or as an adjunctive procedure used to gain bone as part of a larger reconstruction plan. Overall alveolar distraction offers a number of advantages over other augmentation techniques (Bilbao, 2002) (Table 2) (Table 3).

Box 1
General applications for alveolar distraction osteogenesis

- Moderate to severe vertical alveolar bone defects
- Segmental deficiencies of the alveolar ridge
- Narrow alveolar ridges
- Adjuvant to other bone graft techniques
- Gradual vertical movement of ankylosed teeth
- Gradual vertical movement of an osseointegrated implant together with the surrounding alveolar bone

Traditionally alveolar distraction has been used for vertical augmentation of the alveolar ridge but horizontal (Takahashi et al, 2004; Garcia-Garcia et al, 2004; Gaggl et al, 2005) and segmental alveolar distraction (Bilbao et al, 2006; Basa et al, 2007) have also been described. The main indication for alveolar distraction is to manage the vertical defects in the anterior maxilla and mandible. Posterior maxillary defects are best addressed with traditional techniques like sinus lift or bone grafts. Vertical defects of the posterior mandible can be treated with alveolar distraction but if the defect also has a horizontal component a more traditional approach with an onlay bone graft or guided tissue regeneration is recommended (Louis et al, 2008; Gutta & Waite, 2009).

Box 2
Advantages of alveolar distraction osteogenesis for preparation for implant placement

- Simple technique
- Simultaneous augmentation of bone and soft tissues
- Less resorption than traditional bone grafts
- Transport segment can include teeth or implants, facilitating the correction of occlusal or prosthetic defects
- Elimination of donor-site morbidity
- Shorter treatment times compared with traditional bone grafting techniques
- Allows the implementation of complementary techniques when results are not optimal

Box 3
Disadvantages of alveolar distraction osteogenesis for preparation for implant placement

- Patient acceptance and compliance
- Requires careful vector control
- Interference with occlusion might require the construction of protective appliances
- High device cost

In an effort to facilitate the evaluation and treatment of vertical alveolar defects Jensen and colleagues (2008) proposed a classification system where they defined a class I defect as a mild alveolar vertical deficiency with up to 5 millimetres that ideally can be treated by a sandwich osteotomy or more traditional bone graft techniques although distraction can be considered when prosthetic concerns in the aesthetic zone exist. Class II defects consist of a moderate vertical loss of 6 to 10mm that ideally will benefit from alveolar distraction. Class III defects are severe vertical loss greater than 10mm. These defects are treated depending of the bone stock available. If sufficient bone exists, distraction can be done first and definitive alveolar bone form and position can be done with a bone graft, if the amount of bone is not sufficient for distraction, bone augmentation is done first followed by distraction. Finally vertical defects that involved adjacent teeth with significant bone loss are designated a Class IV. In these cases by extracting the affected dentition, the defect will be converted into a defect class II or III making the problem more predictable and easier to resolve.

PLANNING FOR ALVEOLAR DISTRACTION OSTEOGENESIS

Clinical examination will establish a preliminary idea of the patient prosthetic needs, occlusion, as well as the size and shape of the alveolar defect. Maxillary and mandibular models with a diagnostic wax-up will allow corroboration of the clinical findings. Additionally they can be used to fabricate a surgical splint that later could be use for vector control as well as temporary restoration. Models also play an important role in planning for the distraction vector allowing pre-adaptation of the device, decreasing surgical time and identifying possible device interferences with opposing dentition. In more complex cases sterolithographic models are a great option for treatment planning.

The radiographic examination with plain films or CT scan is useful for the alveolar defect assessment but it also allows for planning the length and height of the osteotomy. Of great importance is the amount of bone stock and its relationship with the inferior alveolar nerve, inferior border of the mandible, nasal floor, and maxillary sinus. These factors could limit device placement and/or the distraction procedure. Added considerations should be given for the prophylactic plating of the mandible in which the remaining basal bone is scarce to prevent fracture and retention of compromised teeth adjacent to the distractor procedure to help with vector control. Newer technologies like computer-assisted surgical planning are also being applied to alveolar distraction. (Kanno et al, 2008) (Fig. 3).

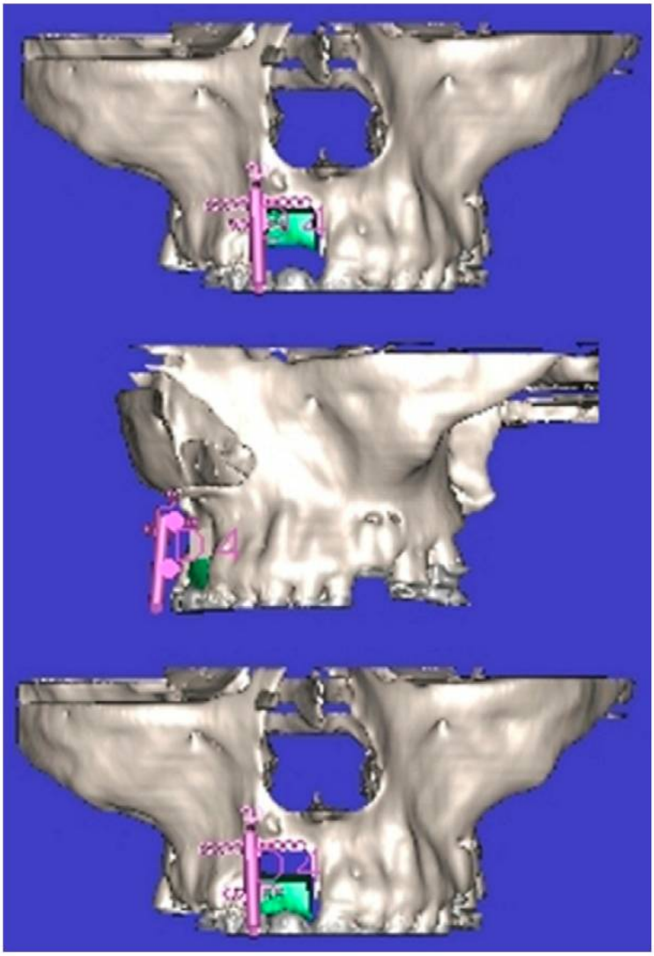

Fig. 3. Alveolar distraction treatment planning using computer-assisted surgical software.

ALVEOLAR DISTRACTION: SURGICAL PEARLS AND PITFALLS

During the different phases of alveolar distraction, there are a series of pearls and pitfalls that will allow a more predictable successful outcome. Furthermore allocating sufficient time for surgical planning is probably the single most important pearl in alveolar distraction.

Incision

- Special consideration should be given for the location of the incision since it will affect the quality of the soft tissue that will be augmented at the end of treatment.
- Remember to use sound surgical principles that will guarantee proper blood supply to the mucosa and bone.
- Careful and conservative dissection will maintain the vascularity of the transport segment, decreasing excessive resorption and avoiding damage to adjacent structures.

Osteotomy and distractor placement

- Use a trapezoidal, semielliptical or L shape osteotomy depending on location.
- Lingually convergent osteotomies will decrease the lingual tipping of the distractor.
- A piezoelectric-assisted osteotomy will allow a deeper cut decreasing the amount of chiseling required.
- A transport segment as big as possible (avoiding compromise of basal bone and adjacent structures), and not just containing cortical bone will avoid a higher rate of resorption.

- Newer modular extraosseous distractors will allow doing the osteotomy after the placement of the device due to their ability to remove the distractor rod.
- Check that the transport segment is able to move freely through the extension of the distractor. (Exception L shape osteotomy)
- In cases of large transport segments consider the placement of two distraction devices. (Fig. 4).
- During extraosseous distraction, vector control can be achieved if the distractor plate for the transport bone is cut longer than usual allowing movement along the buccal bone surface.

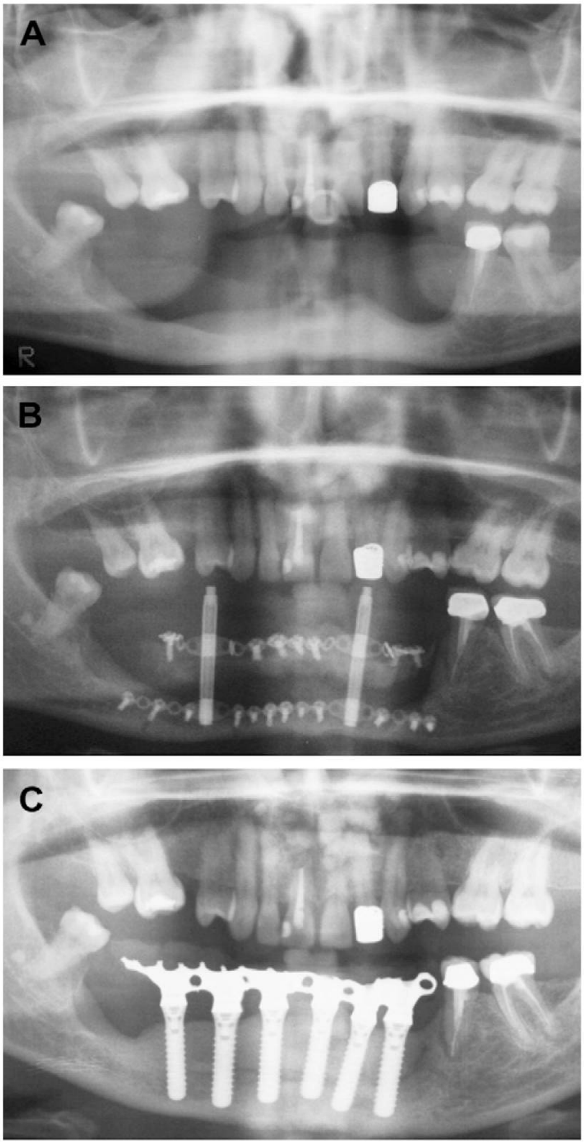

Fig. 4. Placement of 2 distractors for large transport segments. (*A*) Large mandibular defect. (*B*) Placement of 2 distractors. (*C*) Final result after distraction and implant placement.

Distraction phase

- Decreasing the distraction rate and maintaining good oral hygiene will help in the treatment of wound dehiscence.
- Patients should carry a daily a log to record the amount of daily activations.
- Monitor the distraction vector carefully. Several methods for vector control have been described (Herford & Audia, 2004; García-García et al, 2008; Kilic et al, 2009; Mehra & Figueroa, 2008) and they are illustrated in table 4. (Fig. 5).
- When a prosthesis is used as vector control, remember to adjust it daily.
- Always consider overcorrection

Box 4
Methods for vector control in alveolar distraction osteogenesis

- Device modifications
- Orthodontic mechanics: elastic traction, wire stabilization
- Modified prosthesis
- Manual manipulation of the regenerated bone
- Osteotomy after distraction completed

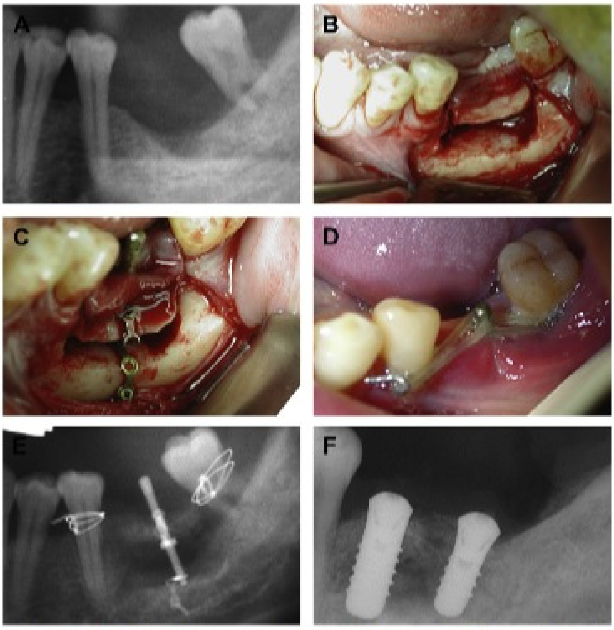

Fig. 5. Vector control. (A) Mandibular vertical defect with severe bone loss involving second molar. (B) Osteotomy. (C) Placement of intraosseous distractor. (D, E) Vector control using orthodontic elastics and compromised tooth. (F) Final result after distraction, extraction of second mandibular molar, and placement of 2 implants.

Consolidation phase

- Covering the distractor rod with a red Robinson catheter will avoid excessive trauma to the surrounding soft tissues.
- Avoid excessive pressure on transport segment when using a temporary prosthesis.
- In selected cases, implant placement during the consolidation phase will allow for stability of the regenerate and maintenance of the distraction vector.

Implant placement

- Thoroughly clean the granulation tissue in the area where an intraosseous distractor was placed. Avoid placement of implants in this area but if necessary use a large diameter implant.
- When possible, use long implants that will engage the native bone. Implant planning software is very helpful in this treatment stage.
- To avoid further resorption do not delay implant loading more than traditional implant protocols.

CLINICAL OUTCOMES IN ALVEOLAR DISTRACION OSTEOGENESIS

Vertical bone gain.

Data of 181 patients from a recent review by Chiapasco and colleagues (2009) showed that the amount of bone gain after distraction osteogenesis had a range of 3-20 mm. Saulacic and colleagues (2008) reported in their systematic review the mean bone gain obtained by different types of distractors; distraction implants 5.02 ± 0.09 mm, intraosseous distractors 7.86 ± 0.36 mm and extraosseous distractors 9.31 ± 0.45 mm. A clinical assessment of 40 patients subjected to an extraosseous distraction showed that the bone augmentation average was 9.5mm in height, showing a 92.5% success rate (Mazzonetto et al, 2005). Kano and colleagues (2007) reported comparable results on bone gain using extraosseous distractors; they also noted that during the consolidation period there was 15% to 25% bone height reduction. These findings are similar to the previous reports in the literature that recommend 20% - 25% overcorrection in vertical alveolar distraction (Saulacic et al, 2005; Wolvius et al, 2007; Ettl et al, 2009). Perdijk and colleagues (2009) pointed out the influence of vector of distraction on vertical gain. They studied 34 cases of alveolar distraction on atrophic mandible in which nearly all patients had lingual tipping of the segment by a mean of 12°. These meant that in those cases only 87% of maximum vertical bone gain could be achieved.

Alveolar distraction compared to conventional bone grafting techniques.

Chiapasco and colleagues (2004) compared alveolar distraction osteogenesis to guided bone regeneration on vertically deficient alveolar ridges. This prospective study evaluated parameters such as, bone resorption of the regenerated ridges before and after implant placement, peri-implant bone loss at one, two, and three years after prosthetic loading of the implant, and success rates of implants. The results suggested that alveolar distraction might offer a more predictable long-term result as far as bone gain maintenance and peri-implant bone resorption. Furthermore implant success rates were significantly higher in the alveolar distraction group. hiapasco and colleagues (2007) also compared alveolar osteogenesis to autogenous onlay bone grafts using the similar parameters. This time they found that bone resorption before implant placement was significantly higher in the autogenous onlay bone graft group. As far as implant success, no difference was encountered between both groups. Uckan and colleagues (2008) also compared alveolar distraction to autogenous onlay graft using complication and implant survival rates. Their results showed a higher complication rate with the alveolar distraction (66.8% versus 33.8%). But they also reported that those complications were minor and easier to treat than the ones in the autogenous onlay graft. Again, implant survival rates were very similar between both groups (91.4% alveolar distraction versus 93.7% autogenous onlay graft). Bianchi and colleagues (2008) in a prospective study comparing alveolar distraction to inlay bone grafting in the posterior mandible showed that although the mean bone gain with alveolar distraction was significantly better (10mm versus 5.8mm), the complication rate was significantly higher in the alveolar distraction group (60%) versus the inlay bone graft group (14.3%).

Two literature reviews on bone augmentation procedures on edentulous ridges for dental implants concluded, it is difficult to demonstrate that one surgical procedure offered better outcomes than another due to the poor methodological quality of the articles published (Chiapasco et al, 2009; Chiapasco et al, 2006) (Table 5). Their recommendation is to give priority to those procedures, which are simpler, less invasive, involve less risk of complications and reach their goals within the shortest time frame.

Table 1
Comparison of augmentation techniques on edentulous ridges for dental implant placement

Technique	Success Rate (%)	Implant Survival (%)
Guided bone regeneration	60–100	92–100
Onlay bone grafts	92–100	60–100
Split ridge	98–100	91–97.3
Alveolar distraction	96.7–100	90.4–100
Microvascular flaps	87.5	88.2

Data from Chiapasco M, Zaniboni M, Boisco M. Augmentation procedures for the rehabilitation of deficient edentulous ridges with oral implants. Clin Oral Implants Res 2006;17(Suppl 2):136–59.

Alveolar distraction on a previously reconstructed site.

Reconstruction of severe maxillary and mandibular defects for dental implants after trauma or tumor ablation is often a difficult task. Case reports in the literature describe the use of alveolar distraction as adjuvant to further enhance sites previously reconstructed with iliac bone grafts (Alkan et al, 2005; Kunkel et al, 2005), scapula free flaps (Hirota, et al., 2008a; Hirota et al, 2008b) and fibular free flaps (Levin et al, 2003; Lizio et al, 2009).

In a retrospective study, Kunkel and colleagues (2005) reported on 4 patients that underwent iliac crest bone graft for mandibular reconstruction after tumour ablation and later alveolar distraction with an intraosseous device. The vertical gain range was from 5 to 9mm and of the 12 implants placed one failed and one had critical bone loss after 40 months of follow up. Hirota and colleagues (2008a; 2008b) described the use alveolar distraction to enhance the mandibular reconstruction done with free scapula flaps in two patients. They reported a vertical gain 9 and 10mm and placement of 9 implants with 100% success rate after 2 years of follow up. In 2009 Lizio and colleagues (2009) used alveolar distraction to increase the vertical bone height on 6 patients after reconstruction with free fibula flaps. The mean vertical bone gain was 14mm (12-15mm). They placed 35 implants of which 4 of them failed during the follow up period bringing the cumulative implant survival to 89%. They also reported one case with fracture of the remaining basal fibula during consolidation.

Success of dental implants in distracted bone.

Prosthetic rehabilitation facilitated by the placement of dental implants is the ultimate goal of alveolar distraction. Controversy still remains with regard to the best time for implant placement.

A prospective multicenter study reported the outcomes of 138 implants placed in distracted bone after 2 or 3 months of consolidation. After a mean follow up of 34 months after prosthetic loading the success rate was 94.2% with a cumulative survival rate of 100%. No statistically significant differences were found between the different centers (Chiapasco et al, 2004).

Using 92 distractor implants on 46 patients with severely atrophic mandibles, Raghoebar and colleagues (2008) reported a survival rate of 97% after a minimum of 62 months of follow up. In a retrospective study Elo and colleagues (2009) compared the implant success rates in distracted bone versus autogenous bone-grafted sites. They placed 184 implants on 65 patients reconstructed with autogenous bone with an implant success rate of 97%. The distraction group contained 56 implants on 17 patients and a success rate of 98%. Again, no statistical difference was noted between groups.

A systematic review on alveolar distraction analyzed a total of 469 implants placed in distracted bone. The mean osseointegration period was 4.59 ± 134 months. The overall survival rate was 97%. They reported 14 implant failures, 10 of them before loading. The mean follow-up was 14.19 ± 11.03 months. This analysis also found no significant difference in implant failure rate associated with location, indication for distraction, latency period and daily rate and rhythm. The mean augmentation rates approached a statistically significant difference: rate on successful implants was 6.79 ± 2.51mm and 8.40 ± 2.31mm on failed implants. A significant difference was encountered in the relationship between implant failures and distraction implants. Consolidation period also showed significant differences, failed implants were placed after 8.10 ± 2.51 weeks compared to 12.43 ± 5.62 weeks for successful implants. Peri-implant bone level was reported for 301 implants. Stable peri-implant bone level was maintained in 285 (95%) of the implants (Saulacic et al, 2008). Recent studies reported peri-implant bone loss values of 0.89 to 1.9mm/year in areas of alveolar bone distraction (Ettl et al, 2009; Polo et al, 2007).

Immediate loading of implants on distracted-bone.

In 2004 Degidi and colleagues (2004) presented a case of immediate loading of implants placed in distracted bone. Although this practice hasn't been popular yet a study was done comparing data from radiofrequency analysis on implants placed in native bone and distracted-bone. Even when the results are significantly inferior for implants placed in distracted-bone, the authors concluded that the values obtained open the possibility towards immediate loading with the outcomes similar to implants in native bone (Bilbao et al, 2009).

Adjunctive techniques to improve the outcomes of alveolar distraction.

Research is being conducted on ways to improve the outcome of alveolar distraction. Robiony and colleagues (2008) reported on their long-term experience on 12 patients after alveolar distraction and a combination of autologous bone graft with platelet rich plasma on severely atrophic mandibles. After performing an osteotomy, the distractor was activated 2-3 mm and the gap was filled with the combination of iliac crest bone graft and platelet rich plasma. Their results showed a vertical bone gain that range from 7 to 10mm with one failed case due to scar retraction. The mean decrease of total bone volume was 2.3% at the time of implant placement. A total of 47 implants were placed, bone loss after 1 year of loading was 0.61mm and 1.51 mm after 5 years. The implant survival and success rates were 97.9% and 91.5%. A double-blinded trial investigated whether low intensity pulsed ultrasound therapy stimulates osteogenesis in mandibular alveolar distraction. Biopsies taken at implant placement after 46 8.1 days of consolidation underwent histological and microradiographic examination. The authors concluded that ultrasound treatment does not appear to stimulate bone formation (Schortinghuis et al, 2008). Dergin and colleagues (2007) reported a case using a novel technique where alveolar distraction was done incorporating a polytetrafloroethylene membrane for protection of the distraction chamber. No defects were noted in the 10mm of newly regenerated bone. Further research is necessary validate this technique. At the time of this writing no human studies using BMP and alveolar distraction have been published in the English literature.

Patient perception and satisfaction after alveolar distraction.

Even when objective clinical data suggest good results, ultimately it is the patient satisfaction which fuels the success of a treatment plan. Using a distractor implant on 46 patients, Raghoebar and colleagues (2008) reported a patient satisfaction of 8.1 ±1.2 (0 completely dissatisfied to 10 completely satisfied) after finalization of the prosthetic treatment. Allais and colleagues (2007) used extraosseous devices in 50 patients to evaluate the patient's perception during and after alveolar distraction. Their findings showed in 76% of the cases the patient reported the surgery as good and bearable (all patients were orally sedated with 15mg of midazolam). During distraction 4% of the patients felt pain, 46% had some difficulty activating the device, with 10% needing extra help. The activation rod was cause of complaint in 52%. Of the 50 patients 27 had to undergo additional autologous bone grafting and 70% of them stated the bone grafting procedure was more painful than the alveolar distraction. Finally 78% of the patients treated with alveolar distraction would undergo this procedure again if it necessary. In a more recent study from the French literature, Castry and colleagues (2009) analyzed the answers of 23 patients after alveolar distraction. They found that 87% of the patients adjusted well to the procedure. Light to moderate pain was reported by 57% and 43% of the patients catalogued the procedure as painful. Fifty seven percent of the patients managed to forget the presence of the distractor and 65% had no problem with the length of the treatment. About 91% of the patients were able to activate the distractor device on their own and finally 52% of the patients reported they would undergo another distraction procedure if necessary.

Complication rates of alveolar distraction.

Regardless of almost 15 years of clinical practice, growing popularity, and newer technologies, alveolar distraction continues to be a challenging procedure. Conventionally alveolar distraction complications have been classified depending on the distraction phases when they occurred: intraoperative, during distraction, during consolidation and post-distraction. They can also be classified as minor complications, or major complications that are more difficult to manage and could jeopardize the distraction procedure. Besides the common complications of any surgical procedure like excessive bleeding, hematoma, infection, paresthesia, there are a set of specific complications for alveolar distraction. These complications, possible causes, management and prevention are illustrated in table 6.

In more recent years several articles have focus on the complication of alveolar distraction. These studies have reported a wide array of complication rates ranging from 36% to 100% (Wolvius et al, 2007; Ettl et al, 2009; Enislidis et al, 2005; Mazzonetto et al, 2007; Saulacić et al, 2007; Perdijk et al, 2007; Günbay et al, 2008). In a comprehensive review of the literature from 1996 to 2008, Saulacic and colleagues (2009) studied the complication rate of alveolar distraction. Their results showed an overall complication rate of 30%. The most common complication was insufficient bone formation after the consolidation period (8%), followed by regression of distraction distance (7%) and problems related to the device (6%). Intraoperative complications include bleeding from the floor of the mouth (4%) and temporary paraesthesia (4%). During the distraction period wound dehiscence was found on 1% of the patients. Pain was reported in 1% of the patients as well as mild soft tissue resistance. Vector deviation was found in 2%. More severe complications were found during the consolidation period including a mandibular fracture rate of 2% and problems related to the device in 6% of the cases. They also found that insufficient bone formation and evidence of complications were significantly related to the type of distractor and augmentation rate higher than 0.5mm daily. The authors concluded although complications in alveolar distraction are frequent, they rarely cause severe problems. They suggested that most of the complications could be related to lack of experience and the learning curve.

Table 6. Complications of alveolar distraction, possible causes, management and prevention

Phase	Complication	Causes	Management	Prevention
Intraoperative	Inability to mobilize the transport segment	• Incomplete osteotomy • Poor osteotomy design with lack of divergence	Retrace osteotomy	Better execution and planning of the osteotomy
	Fracture of the transport segment	• Lack of sufficient bone stock • Excessive force during mobilization of the osteotomy	Small fractures: removal of fragment, relocate distractor arms to new position (extraosseous devices) (Fig. 6) Large fractures: suspension of distraction procedure, osteosynthesis, possible bone graft (Fig. 7)	Cautious osteotomy and mobilization of the transport segment
	Fracture of the basal bone	• Lack of sufficient bone stock • Excessive force during mobilization of the osteotomy	Reduction and fixation of fracture segments	Careful planification and execution of osteotomy
	Occlusal interference of distractor rod	• Lack of proper planification	Shortening or reposition of distractor rod	Careful planning using cast models
	Damage to adjacent structures	• Improper surgical technique	Conservative	Careful planning and execution of osteotomy
	Distractor fracture (extraosseous devices)	• Excessive bending of distractor arms	Change distractor device	Use cast models to prebend device avoiding excessive manipulation
During distraction and consolidation	Wound dehiscence	• Excessive tension at closure • Poor soft-tissue coverage	Reduction distraction rate, secondary suture	Smaller distraction rate
	Mucosa perforation	• Sharp bony edges in the transport segment	Trimming sharp edge	Smoothing alveolar ridge irregularities
	Premature consolidation	• Lack of compliance of the patient • Excessive latency period • Slow distraction rate	Repeat osteotomy	Correct patient selection and patient education Decrease latency period Increase distraction rate
	Distractor failure	• Loosening due to poor bone quality on the transport segment • Distractor fracture	Distractor removal Consider distractor replacement or bone grafting procedure (Fig. 8)	Avoid excessive manipulation of devices
	Incorrect distraction vector	• Excessive pull from lingual and palatal periosteum, muscle insertions • Incorrect placement of the distractor	Vector control (see Table 1)	Careful planning, close monitoring
	Transport bone resorption	• Interruption of blood supply due to excessive reflection of perforation of tissue	Consider overcorrection	Conservative
After distraction	Bone defect	• Multifactorial	Consider bone grafting	Good alveolar distraction technique

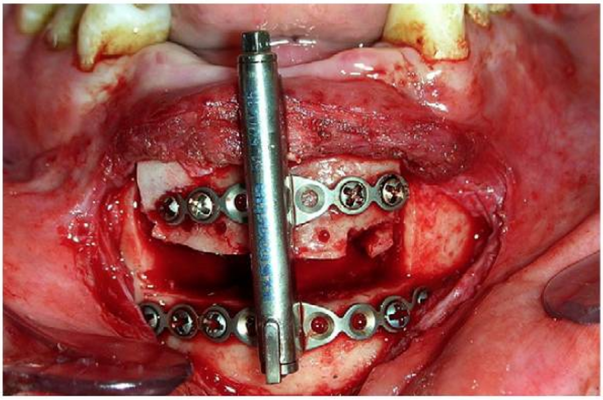

Fig. 6. Small fracture of transport segment treated by repositioning the distractor device.

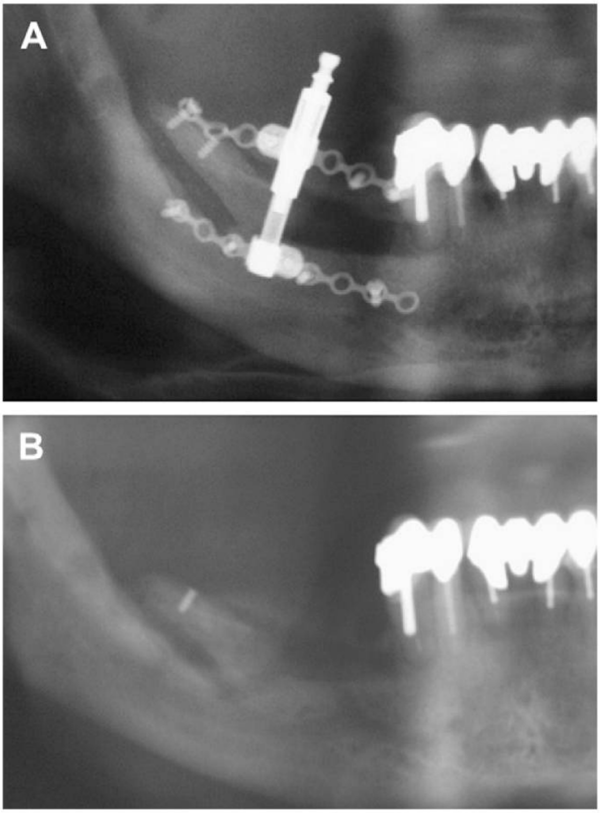

Fig. 7. (*A*, *B*) Panoramic radiographs showing large fracture of transport segment that required the suspension of the procedure.

2

Justification and objectives

2. Justification and objectives

A comprehensive review of the existing literature reveals sound clinical and histological evidences supporting the techniques for bone and soft tissue augmentation based upon the principles of histogenic distraction. The results obtained by these procedures in the maxillofacial area not different from those previously reported for other regions of the human body.

However, most of the papers reviewed for the present investigations do not take into account the mechanical aspect of the implant-new bone complex. This lack of information makes the use of histogenic distraction a clinical challenge in situations where immediate implant load and function is required and also when rehabilitating oral cancer patients.

Primary stability –a mechanical parameter- permits determining the amount of load the fixations can withstand before osseointegration occurs. Osseointegration is an objective phenomenon consisting in a histologically quantifiable union measurable in terms of percentage of implant surface contacting with bone.

Cancer patients with tissue defects resulting from tumour resection have improved their life expectancy with multidisciplinary treatment approaches, so to increase life quality by improving functional and aesthetic reconstruction has now become an objective for every treatment. Histogenic distraction techniques contribute to this aim with less morbidity and economic costs than conventional methodologies. Careful and thorough case planning -especially the control of the distraction vector- has proved to be a cornerstone for treatment success and minimization of complications.

A preliminary systematic literature review disclosed unsolved problems on the surgical use of these techniques: it seems necessary to determine the degree of primary stability provided by osseodistraction-generated bone and its applicability in clinical situations where maxillary reconstruction procedures require minimal morbidity, such as cancer patients. Thus, the aims of this research project were:

1. To assess the degree of primary stability of implants inserted in osseodistraction-generated bone in comparison to native bone.
2. To assess the surgical feasibility of osseodistraction techniques in patients with maxillofacial neoplasms and to establish a protocol aimed at minimizing its morbidity.

3

Assessment of dental implants stability in osseodistraction-generated bone. A resonance frequency analysis

3. Assessment of dental implants stability in osseodistraction-generated bone. A resonance frequency analysis

Abstract

Objectives: to determine the implant stability in osseodistraction-generated (ODG) bone after a 2-month consolidation period, assessed by resonance frequency analysis (RFA).

Materials and methods: Twenty healthy, non-smoker female patients receiving 71 dental implants, 39 placed in native bone and 32 in ODG bone after an 8 week consolidation period. Primary and secondary stability of the implants were assessed by means of the Osstell® *mentor* device. The average value of 6 measurements was considered for the statistical analysis at each time point.

Results: The age of the patients that received implants in ODG was not significantly that of those receiving implants in pristine bone (48.0±10.9); (X= 1.6; 95%CI=-7.7- 10.9).

Although implants placed in both bone types indicated good primary stability, a statistically significant difference in favour of those implants places in pristine bone could be identified OD (X_i-X_j= 3.4; 95%CI= 1.7-5.8). After a 1.5 months integration period, none of the implants failed, but implant stability still recorded higher values for implants located in pristine bone (X_i-X_j = 2.5; 95%CI= 0.5-4.4).

A positive linear correlation could be established between the ISQ values at implant placement (primary stability) and post-integration ISQ score (secondary stability) for both bone types, but only a 16% of the post-integration ISQ in the ODG bone can be attributed to the primary stability.

Conclusions: under the limitations of this study, OD-bone offers –after a 2 month consolidation period- a high primary and secondary stabilities after implant placement.

Introduction

Osteogenic distraction (OD) is defined as the creation of neoformed bone and adjacent soft tissue after the gradual and controlled displacement of a bone fragment obtained by surgical osteotomy (Cano et al, 2006b; Cope et al, 1999). The use of this technique in the maxillofacial area was firstly reported in 1973, when Snyder et al. (1973) described an experimental application in dog mandibles. Its first clinical indication was published in 1992 for the treatment of patients with hemi facial microsomias using an extra oral distractor (McCarthy et al, 1992).

One of the most relevant applications of this technique in dental implantology is the correction of segmental deficiencies of the alveolar ridge that compromise implant placement either aesthetically of functionally (e.g.: unfavourable crown-implant index) (Cano et al, 2006b; Urbani et al, 2001).

Despite the obvious benefits of this procedure, there still are biological factors like the so called “consolidation period” (time between the distraction phase and the withdrawal of the distractor (Cano et al, 2006), that may severely compromise the quality of the newly generated bone (Cope et al, 1999). This parameter has only been evaluated in animal models (sheep and dogs) by means of densitometry (Frahadieh et al, 2000), computerised tomography (Smith et al, 1999), conventional radiology (Cope & Samchukov, 2001) or histomorphometry and immunohistochemistry (Cano et al, 2006; Carls et al, 1997, Cope & Samchukov, 2000; Sawaki et al,

1996) and in humans by analysis of biopsy material taken previously to implant placement (Zaffe et al, 2002; Raghoebar et al, 2002).

This background has not produced unequivocal evidence on the optimal time for implant placement in newly distracted bone, and periods ranging between 3 weeks and 3 months have been suggested (Oda et al, 2000; Nosaka et al, 2000; Gaggl et al, 2000); thus, the question on the length of the consolidation period the surgeon should allow for still remains. Different histological studies have proved that after an 8 week consolidation period, the bone generated by OD elicits high density (Cope & Samchukov, 2001; Oda et al, 2000) and the entire gap was filled with lamellar bone (Cano et al, 2006; Carls et al, 1997; Cope & Samchukov, 2000). However, there is a lack of clinically objective information on implant stability after this consolidation period.

The aim of this study has been to determine the implant stability in OD-generated bone after a 2-month consolidation period, assessed by resonance frequency analysis (RFA). Secondary objectives were to compare the stability of native bone *versus* OD-generated bone and to study the correlation between primary and secondary implant stabilities in both types of bone.

Patients and methods

A longitudinal intervention study was designed to compare two groups of patients (native bone and osseodistraction generated bone).

Sample characteristics

Twenty healthy, non-smoker female patients requiring osseointegrated dental rehabilitations entered the study. The mean age of the sample was 48.6±9.9 years (minimum 34, maximum 68).

After clinical examination and treatment planning, 14 patients were considered suitable for implant placement following the conventional protocols, whereas 8 showed severe atrophy of the alveolar ridge that required correction by OD techniques before implant placement was feasible.

The patients in the sample received 71 Straumann® (Institut Straumann AG, Basel, Switzerland) titanium dental implants (average 3.2 ±1.4 implants per patient (minimum 1, maximum 6). All implants were 10 mm long and 4.1 mm of RN diameter with SLA® surface. A total of 39 implants were placed in native bone (25 in the forth sextant and 16 in the sixth) and 32 in newly OD-generated bone (12 in the forth sextant and 20 in the sixth).

Surgical technique

The surgical protocol followed the general surgical protocol for distraction osteogenesis for posterior mandible, considering the size and width of the transport segment, the position of the lower alveolar nerve and the available inter-occlusal space (Batal & Cottrell, 2004).

Local anaesthesia was applied by means of a block technique using a solution of articaine with epinephrine 1:100,000 and midazolam sedation. The incision was placed in the attached gingival when possible, and tissue is reflected inferiorly up to a point where horizontal bony cut can be made for the creation of the transport segment and osteotomy lines were marked. The extraosseous device

(Track-Plus; KLS/Martin, Jacksonville, Florida, USA) was checked and modelated at this stage. The distractor was withdrawn and the osteotomy completed using a piezoelectric instrument (Piezosurgery, Mectron S.p.a., Carasco (Ge), Italy), under copious irrigation and a chisel. Vertical osteotomies were designed apically convergent to allow displacement of the transported segment and lingually convergent to prevent lingual tipping of the transport segment during distraction. An L-shaped osteotomy was eventually used (a small vertical osteotomy is made in the anterior region of the edentulous ridge, and a long horizontal osteotomy extended from the vertical osteotomy back to the posterior edentulous ridge) (Batal & Cottrell, 2004). Once these procedures were completed, the distractor was placed and the absence of interferences ensured.

The latency period –time from surgery to commencement of distraction- was five days. The distraction phase –period in which traction is applied to the transport segment and the formation of new bone commences- was 7 to 10 days to obtain an average bony gain of 6 mm. The rate of distraction –distance the bone is lengthened each day- was 0.9 mm/day with a rhythm of distraction –number of distraction events per day- of 3 movements of 0.3 mm/day. The consolidation period –that follows active distraction and continues until the device is removed- was 8 weeks. After this period, the distractor device was removed and the implants placed, under local anaesthesia, in the same surgical act (Fig. 1 and 2).

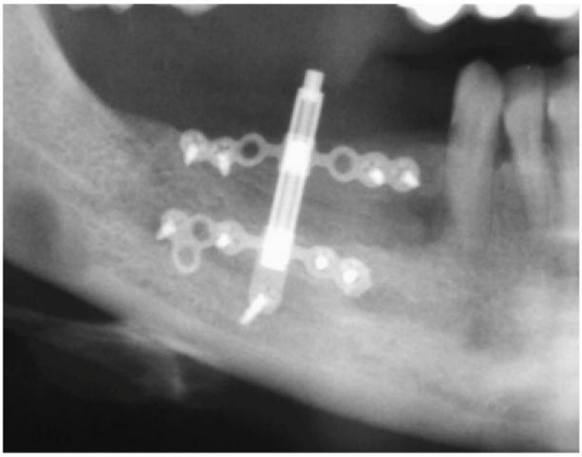

Fig. 1. Distractor in place after a 8 week consolidation period

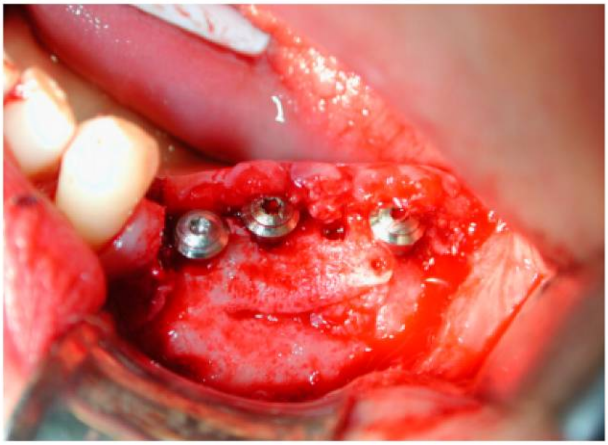

Fig. 2. Implants placed after removal of the distractor

Implant stability determination

Implant stability was assessed by means of the resonance frequency analysis taking the average value of 6 measurements performed by the Osstell® *mentor* (Integration Diagnostics AB, Göteborg, Sweden) device directly over the fixation.

The Osstell® *mentor* is a non-destructive system aimed at determining dental implants stability within the oral cavity and maxillofacial area based upon the assessment of the resonance frequency (FRA) (Meredith et al, 1996). This system includes the use of the Smartpeg® Integration Diagnostics AB, Göteborg, Sweden) appliance that is fixed to the dental implant through an integrated screw. The Smartpeg® is activated by a magnetic pulse sent from the probe located on the hand-held part of the instrument. The measuring probe integrated in the Osstell® *mentor* device is maintained close to the Smartpeg® but ensuring no contact between them. Then, an acoustic signal confirms the measurement (www. osstell.com). The frequency of the resonance, which is the value allocated to the stability of the implant, is calculated from the response signal. The result of the measurement is displayed by the device in ISQ (implant stability quotient) units that range from 1 to 100 (Aparicio et al, 2006).

Statistical analysis

Statistical analysis was performed by means of a SPSS®+ 12 (SPSS Inc. Chicago, Ills. USA) statistical package and Epidat 3.1 (Xunta de Galicia, OPS/WHO, Santiago de Compostela, Spain) for Windows. A descriptive statistical analysis was performed using the mean of the distribution as a centralization parameter and the standard deviation as a spread indicator. The non-parametric Mann-Whitney U test was employed for comparison of the means; together with the confidence interval determined for the difference of the means. Pearson correlation coefficient was chosen as a measure of linear association between quantitative variables (ISQ) at the moment of implant placement (primary stability) and post-integration ISQ (secondary stability). In order to establish the influence of the primary stability (predictor variable) on the secondary stability (response variable), a linear regression and its coefficient (R^2) were used. The significance level chosen was 5%. Two-side determination was used in all tests.

Results

The age of the patients that received implants in OD-generated bone was 49.6±8.4, which was not significantly different from that of the patients receiving implants in pristine bone (48.0±10.9); (X_i-X_j= 1.6; 95%CI=7.7- 10.9).

The resonance frequency analysis at implant placement in OD-bone showed a mean ISQ of 73±4.1, whereas the implants placed in pristine bone elicited a 76.8±4.4 ISQ value. Although both values indicate good primary stability, a statistically significant difference in favour of those implants places in pristine bone could be identified OD (X_i-X_j= 3.4; 95%CI= 1.7-5.8) (Fig.3).

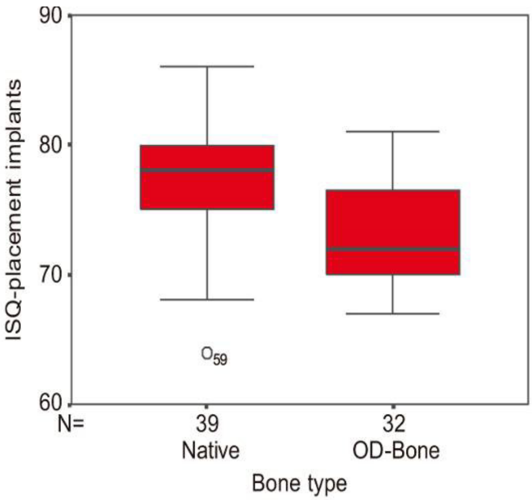

Fig. 3. RFA values for primary stability of the implants

After a 1.5 months integration period, none of the implants failed, and the mean ISQ of OD-bone was 77.2±4.0 for 79.7±4.2 of the implants placed in pristine bone. Again, implant stability was higher for implants located in pristine bone (X_i-X_j= 2.5; 95%CI= 0.5-4.4) (Fig.4).

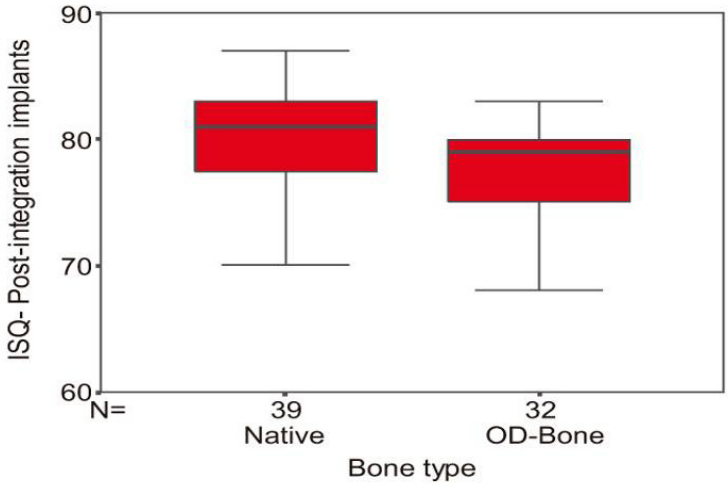

Fig. 4. RFA values for secondary stability of the implants

A positive linear correlation could be established between the ISQ values at implant placement (primary stability) and post-integration ISQ score (secondary stability) both for the OD-bone OD (r_{xy} = 0.4; p=0.02) and pristine bone (r_{xy} = 0.61; p=0.000). However, it is worth noting that the regression line for native bone had a determination coefficient (R^2) of 0.37, which indicates that a 37% of the variation of the post-integration ISQ can be explained by the initial ISQ (primary stability). In OD-bone, this coefficient was 0.16; thus only a 16% of the post-integration ISQ can be attributed to the primary stability (Fig. 5).

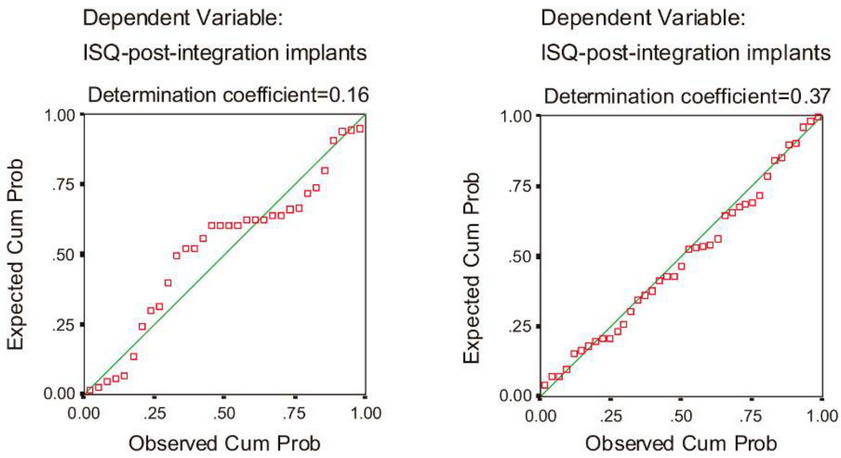

Fig. 5. Linear regression adjustment for ISQ values in ODG (left) and native (right) bones

Discussion

Distraction osteogenesis can efficiently augment bone vertically (Esposito et al. 2003). This technique is highly predictable with reported success rates from 96 to 100% (Chiapasco et al, 2001; Chiapasco et al, 2006). Nowadays, studies on alveolar distraction remain at experimental stage and are scarce in scientific literature (Cano et al, 2006; Cano et al, 2006b).

Implant survival rate in OD-bone appears comparable to that of non-distracted bone (Chiapasco et al, 2006; Block et al, 1998; Block et al, 2000; Jensen et al, 2000; Rachmiel et al. 2001), with percentages to 90.4 to 100% (Chiapasco et al, 2006). However, there is not enough scientific evidence to allow for individualised protocols for implant insertion that take into account biological or biomechanical factors involved in OD, like consolidation time, distractor design, age, gender, anatomical site, bone density of general status of the patient (Cano et al, 2006; Cope et al, 1999; Cano et al, 2006b).

Despite the accurate knowledge of what levels of primary stability can be obtained in different jawbone regions and of what particular factors influence primary stability (Ostman et al, 2006), this factor still impairs implant survival (Stanford 2005) and it is largely a mechanical parameter determined by bone density, implant design and surgical technique (Glauser et al, 2004). In OD-generated bone, some other factors should be added to this list: gender -greater stability in males- (Ostman et al, 2006; Zix et al, 2005) and anatomical site –higher stability in mandible- (Ostman et al, 2006; Ersanli et al, 2005).

The RFA is a non-destructive method extensively used in clinical research to monitor implant stability due to its high reproducibility (Aparicio et al, 2006). RFA has also been used to assess the osseointegration period, immediate load feasibility and follow-up studies aimed at predicting implant failure (Ersanli et al, 2005; Huang et al, 2002). RFA values/ISQ levels correlate positively with bone quality (Ostman et al, 2006; Bischof et al, 2004; Balshi et al. 2005) and is affected by factors such as bone tissue features, implant sink depth, diameter or type of surface (Aparicio et al, 2006) and has to be calibrated for each implant system separately (Ersanli et al, 2005).

In order to control confounding factors that may influence the determination of primary stability of the implants, restrictive inclusion criteria were established that reduce the sample to female patients with posterior mandibular implants. The cornerstones for increasing accuracy at implant stability determination were the use of a high precision automatic device (Ostell® *mentor*) with periodic calibrations and repeated measurements to reduce random errors. However, and due to the homogeneity of the sample, generalization of the results reported in this study to other clinical situations should be done with caution.

Metalloproteinase analysis in animal models (sheep) showed that distracted bone was remodelled until 9 months after distraction. After this period, OD-bone followed a stable remodelling pattern similar to that of non-distracted bone (Marucci et al, 2001). However, there is a generalised trend towards diminishing this consolidation period to avoid infectious complications, but it is mandatory to keep the distractor in place long enough to obtain a tissue able to withstand the biomechanical implications of implant placement (Cano et al. 2006; Cano et al. 2006b). A three week consolidation period offers an immature bone that starts to form columns from the borders of the distracted area (Nosaka et al, 2000). After a 3 month consolidation period, the cumulative success rate of dental implants was 100% in human models (Chiapasco et al, 2001; Chiapasco et al, 2006; Rachmiel et al. 2001).

Histological studies performed in humans have proved the presence of bone trabecula parallel to the distraction vector and support the criterion that an 8 week consolidation period is enough for implant placement (Cano et al, 2006; Zaffe et al, 2002; Raghoebar et al. 2002). In this series, with the same consolidation period, a high primary stability was obtained only slightly lower than that achieved in native bone. ISQ values obtained both for native and OD-bone are well within the limits considered suitable for immediate implant loading. This consolidation has granted the maintenance of the regenerated bone without collapse of fracture of the area. Our results agree with those of Rachmiel who, with an identical consolidation period and a 6-20 month follow-up period after OD, reported a single failure (out of 22 implants) due to improper distracted segment stability (Jensen et al. 2000).

Previous reports on native bone using RFA have showed a decrease in bone-implant stability in the first month after implant placement (Balshi et al, 2005), followed by increases in stability in the second and third months, suggesting a process of adaptative bone remodelling around the implant (Ersanli et al, 2005; Balshi et al, 2005). In this series, after a 1.5 osseointegration period, the secondary stability scores were high, with ISQ values slightly over those elicited at implant placement. There also seems to exist a better positive linear association in native bone between primary and secondary implant stability.

It is concluded that, under the limitations of this study, OD-bone offers –after a 2 month consolidation period- a high primary and secondary stabilities after implant placement.

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4

Pearls & pitfalls in alveolar distraction

4. Pearls & pitfalls in alveolar distraction

Introduction

The use of distraction osteogenesis techniques to reconstruct the alveolar process dates from 1996. It is mostly recommended in order to increase the height of the available bone while improving the soft tissues. The technique involves fracturing the alveolar process and subsequently separating the fragments by means of a device so as to place the transported portion in a position that is suitable for rehabilitation or for the insertion of dental pieces or implants in an optimal position. The removal of the donor area and the simultaneous increase of the soft tissue are, in theory, an advantage as compared to traditional bone graft techniques.

Yet, the inadequate recommendation of the technique and the disregard of certain technical details lead to complications and in most cases the loss of the distraction vector is rather relevant (Box 1 and 2).

Practical Preoperative Tips

1. An adequate occlusal and model study, using radiology software, is essential in the planning and localisation of the parenchyma to be avoided; and the same goes for the pre-modelling of the distractor.
2. It is convenient to plan the number of implants to be inserted, the number of pieces to be rehabilitated and, hence, the length of the segment to be distracted in advance.
3. The patient must be adequately instructed before the surgery and he must be acquainted with the device and its operation before its attachment.
4. A comprehensive presurgical study must be carried out and, in most cases, the surgical intervention can be implemented with local anaesthetics and sedation, the cooperation of the patient being very important in order to check the vector obtained during the distractor modelling phase.
5. If devices are used to control de distraction vector, they should be adequately planned beforehand.

Practical Operative Tips

1. The incision must allow for an adequate access, protecting the attachment and the implementation of the osteotomy through direct visual control. It may be crestal or at the back of the oral vestibule.

2. It is convenient to spot the anatomic accidents and parenchymal structures that might be damaged in advance.
3. The osteotomy may be either trapezoid, converging towards the lingual side of the maxilla and with the broadest part on the occlusal, or semi-elliptical in the case of big segments or of L-shaped segments if it affects the posterior sectors of the mandible.
4. In the posterior sector of the mandible it is convenient to place the basal attachment plate beneath the point of emergence of the mentonian nerve in order to prevent lesions on the dental nerve.
5. The osteotomy must be as complete as possible in order to prevent bad splits whose length might be somewhat inferior to that of the distraction plate in the case of yuxtaosseus devices, so that its ends may rest upon the mesial and the distal ridges, blocking the retroclination forces exerted by the soft parts.
6. Always check that the fragment is completely liberated, yet attached to soft tissues so as to guarantee an adequate blood supply.
7. Check the operation of the distractor before making the suture, it must move without bone interference.
8. Attach the vector control system at the very beginning
9. It is convenient to protect the shank in order to avoid recumbency; the tip of a urinary catheter can be used as hood.

Practical Postoperative Tips

1. Cold therapy is mandatory the day the surgery takes place.
2. Antibiotics and anti-inflammatory non-steroid drugs can be prescribed for the first days.
3. Five to seven days after the lag phase the activation of the distractor will start at 0.5 to 1.5 mm per day. It is advisable to implement several low-range movements and to alternate three days of distraction and one day of contraction, considering, necessarily, a 20% overcorrection.
4. The patient must be controlled at least twice a week in order to check whether the process evolves without complications.
5. After the distraction phase, the consolidation phase starts. It will last ten to twelve weeks and the evolution of the distraction callus will have to be radiologically controlled.
6. Should there be any problem to keep the distraction vector, we can decide whether to attach the implants without removing the device or whether to remove the distractor earlier in order to modify the callus and place the segment in a more favourable position
7. The data concerning the stability measured with resonance frequency show that it is possible to implement the immediate loading in specific cases. Still, the implant integration phase and its loading will be governed by the usual protocols so as to allow for an adequate bone remodelling.

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BOX I **PEARLS**

- Case planning and the exhaustive control of the distraction vector are of paramount importance. Ad-hoc software is highly useful for this.
- When the segments to be treated are too long it is preferable to attach two distraction devices.
- The use of the piezoelectric instruments in osteotomy allows for almost complete, highly precise osteotomies reducing the need to use burrs and, hence, improving patients' comfort.
- Making distraction-contraction movements reduces tension in soft tissues and the recurrence rate.
- The use of orthodontic appliances, elastics and cast devices helps keeping a stable distraction vector, which must be controlled until implant placement.

BOX 2 **PITFALLS**

- Over-indication and the lack of surgical training are the main causes of complications in this technique.
- If the minimum size of the segment is not observed, the risk of lesion of adyacent tissues and bone sequestrum occurrence increases.
- Never finish the surgical intervention before having checked the absence of bone interference and the absence of interference between the device and the opposite arch.
- Visits should be programmed at intervals of no more than 5 days

5

Lateral transport osteogenesis in maxillofacial oncology patients for rehabilitation with dental implants

5. Lateral transport osteogenesis in maxillofacial oncology patients for rehabilitation with dental implants

Abstract

Four patients treated using lateral transport osteogenesis were retrospectively studied (mean age 55; range 41-62). Complete reconstruction of segmentary defects after surgical and radiological cancer treatment on maxilla (up to 30 mm) and mandible (55 mm, without radiotherapy) was achieved. No relevant intra- or post-operative complications occurred. No differences on implant survival were observed between patients who had received radiotherapy and those who had not. TDDO can be considered a recommendable reconstructive option after oral cancer treatment –including radiotherapy- particularly for high-surgical-risk, collaborative patients.

Introduction

Many maxillofacial tumours are diagnosed at advanced stages with frequent mandible/maxillary involvement, resulting in marginal or segmental resection with adjuvant radiotherapy. The vascularised free-osseous flap (VFOF) is the current gold standard for reconstruction in these cases (Constantino et al, 1990) although this procedure is far from ideal for patients with increased surgical risk and for those requiring an adequate soft tissue quality before implant insertion, as VFOF results in a too thick overlying soft tissue without peri-implant attached gingival (Constantino et al, 1990; Jegoux et al, 2010).

Osteogenic distraction procedures, like transport-disc-distraction-osteogenesis (TDDO), may solve these shortcomings as no statistically significant differences could be found between autogenous bone and distracted bone sites in terms of stability and implant survival rate (Assuntina et al, 2007;.Bilbao et al, 2009; González-García & Naval-Gías, 2010; Vega & Bilbao, 2010). The main limitation of such techniques in these situations would come from the effects of radiotherapy, applied either before or after distraction, on the regenerated bone (González-García et al, 2007).

This paper reports on the use of lateral transport osteogenesis in cancer patients who have undergone maxillo/mandibular resections and on the implant survival rate in the generated bone.

Patients and methods

Four patients with segmental defects after oncological resection were retrospectively studied (mean age 55; range 41 to 62) (Table 1). The lateral bone transport technique was used to reconstruct the maxillary and mandibular bone defects in all cases: periosteum over the designed transport disk was preserved during the procedure to ensure vascularity, and the ostectomy was performed by means of a piezoelectric device (Piezosurgery System; Mectron Medical Technology, Carasco, Genoa, Italy) 7 to 15 mm away from the defect to create the transport disk. The MODUS modular distractor (Medaris

AG, Basel, Switzerland) was used in the maxilla and the KLS system (Martin intraoral distractor, USA) in the mandible. The devices were not activated for 5-6 days (latency period). The chosen distraction/contraction protocol progressed at a distraction rate of 0.75 mm a day for three days to contract another 0.75 mm on the forth day -in order to avoid excessive tension on the soft tissues- and continued until the device's distal stump was reached. A consolidation period of 8 to 12 weeks was allowed, and the dental implants (4.1 mm diameter, 12 mm long, Esthetic Plus, Straumann AG, Waldenburg, Switzerland) inserted. The fixations were loaded sixteen weeks after placement.

Figure 1: Distraction device MODUS

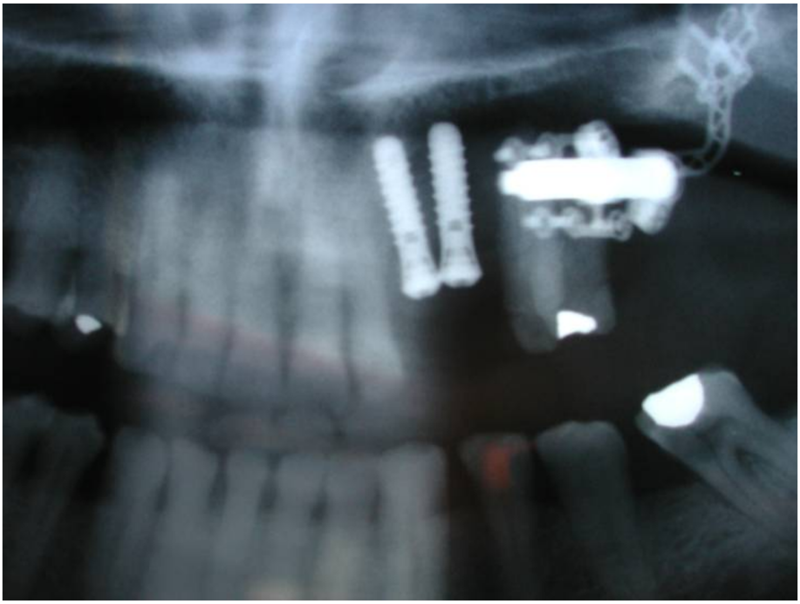

Figure 2: Dental implants inserted. The distractor is not retired.

Figure 3: Panoramic X-Ray control one year after insertion of implants and prostheses.

Table 1. Patients' clinical and pathological features.

Patient ID/ Gender/ Age	Primary Diagnosis	Defect Location	Local Treatment	Neck Treatment	Radiotherapy	Secondary Diagnosis
1/male/61	SCC	Maxilla (right)	Maxillectomy and reconstruction by miofascial temporal flap.	Ipsilateral radical neck dissection.	Yes (60GY)	Neck recurrence alter 12 months
2/female/41	Chondrosar coma	Maxilla + malar (right)	Maxillectomy and reconstruction by scapular flap (failed). 2nd reconstruction by radial antebrachial flap.	Ipsilateral neck dissection	Yes (60GY)	TMJ ankylosis post-radiotherapy
3/male/56	SCC	Maxilla (left, rear)	Maxillectomy and reconstruction by Bichat pad flap.	Ipsilateral neck dissection	No	Neck metastases
4/male/62	SCC	Mandible (left)	Resection and primary closure	Ipsilateral neck dissection	No	-

SCC: squamous cell carcinoma.

Results

The results are summarized in table 2. The use of lateral transport osteogenesis techniques permitted complete reconstruction of segmentary defects after surgical and radiological cancer treatment on maxilla (up to 30 mm) and mandible (55 mm, treated without adjuvant radiotherapy). None of the cases showed relevant intra- or post-operative complications. No differences in terms of implant survival were observed between patients who had received radiotherapy and those who had not.

Table 2. Lateral transport osteogenesis description.

Patient	Defect site	Defect Length (mm)	Transport Disk Length (mm)	Distracted Bone Length (mm)	Consolidation Period (wk)	No. Implants (survival %)	Complications	Follow-up (yr)
1	Maxilla (right)	22 30	7	30	10	4 (100)	No	9
2	Maxilla (right)	13 15	15	15	8	2 (100% in distracted bone)	1 pterigoid implant lost (native bone)	5
3	Maxilla (left)	24 30	12	15	10	2 (100)	No	3
4	Mandible (left)	44 55	10	55 44	12	3 (100)	No	5

wk: week; yr: year; No: number

Discussion

TDDO has been recently recognised as a valuable alternative for mandibular reconstruction after surgical section and radiotherapy, producing functional bone similar to residual bone (Assuntina et al 2007; Bilbao et al, 2009; González-García & Naval-Gías, 2010; Vega & Bilbao, 2010; González-García et al, 2007; Seitz et al, 2010). Short case series, mostly reporting on mandible, show success rates close to 83% (González-García & Naval-Gías, 2010), but the information available about this procedure for maxillary reconstruction and the influence of radiotherapy on its results is limited. This may well be due to the difficulty to obtain an adequate morphology on curved segments, which could make a 2-phase distraction mandatory. Moreover, implants placed in maxilla after radiotherapy have proved a poor survival rate (59%) (Visch et al 2002), although studies on this situation are so scarce that no definitive conclusions can be drawn.

In this series, all 6 implants inserted in patients who had received maxillary radiotherapy (patients 1 & 2) elicited a 100% five-year survival rate, despite the fact that the described procedures are different from more conservative protocols (0.5 mm a day and/or twice long consolidation period) reported in the literature (Saulacic et al, 2009).

Our results, with the inherent limitations to such a small case series, seem to support the idea that TDDO can be considered a recommendable reconstructive option, both for maxilla and mandible, in patients having undergone oral cancer therapy –including radiotherapy- particularly for high-surgical-risk, collaborative patients.

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6

Perspectives on alveolar distraction

6. Perspectives on alveolar distraction

Distraction is a biological process of bone formation occurring between the surfaces of vital bone segments which are gradually separated by a traction (Ilizarov, 1990) process where the soft tissues accompany bone throughout the process.

The application of histogenic distraction techniques to the reconstruction of the alveolar ridge dates back to 1996, when Chin -in humans- and Block et al. (1996) –in dogs- reported alveolar ridge augmentations using techniques already described for the facial skeleton.

This technique permits reconstruction of the alveolar process without bone grafting (Hidding et al, 1999) and, although there is not enough scientific evidence to claim superiority over other approaches, it may be considered the treatment of choice (Vega & Bilbao, 2010) for 6 to 10 mm vertical defects (Jensen & Block's type II (Jensen & Block, 2008)) defect). For larger defects, the amount of remnant bone should be carefully assessed.

In the early ages of the technique, many case series reported high percentages of complications, mostly minor in nature (García et al, 2002), but able to seriously hamper the treatment (Perdjick et al, 2007; Enislis et al, 2005). Many of these complications could have been minimized by a comprehensive treatment planning.

The widespread use of three-dimensional image studies and stereolithographic models ease surgical planning at a first stage, although the particular anatomical conditions of the alveolar bone make difficult an accurate prediction of the final results of the treatment.

As early as 2000, Gaagl et al reported on a study performed on nine patients where surgical planning for placing distractor implants was undertaken using models produced after three-dimensional axial computerized tomographies. This technique was considered the gold standard for craniofacial distraction at the time, despite the possibilities of virtual surgery as the main tool for surgical planning had already been suggested. No attempt to control the distraction vector was mentioned in this report, which posteriorly proved to be a key factor to consider.

Kanno (2008) described a treatment planning method for bidirectional distractors (V2-Alveolar Distraction System. Medartis AG, Basel, Switzerland) using the SimPlant CMF/OS Pro software (Materialise, Leuven, Belgium). His paper also reports on important discrepancies between the final result of the treatment and the aimed objective despite having corrected to the maximum extent possible in all cases. This event is due to the tension exerted by the soft tissues, particularly the palatal mucosa and surrounding muscles (Iizuka et al, 2005), and made some authors suggest a palatal approach for distraction in the premaxilla region (Loubel et al, 2007).

This phenomenon of variation and loss of the vector is more frequent when using intraosseous type distractors (Uckan et al, 2007).

USEFULNESS OF GUIDED SURGERY FOR ALVEOLAR DISTRACTION

Study of the bone defect

Provision of a high-precision communication channel between professionals (Loubel et al, 2007)

Implant placement planning according to the up-and-down (Rosenfeld et al, 2006) philosophy (Fig 1).

Figure 1: Planning of implants and bone segment

Design of the osteotomy (size and shape) (Fig 2)

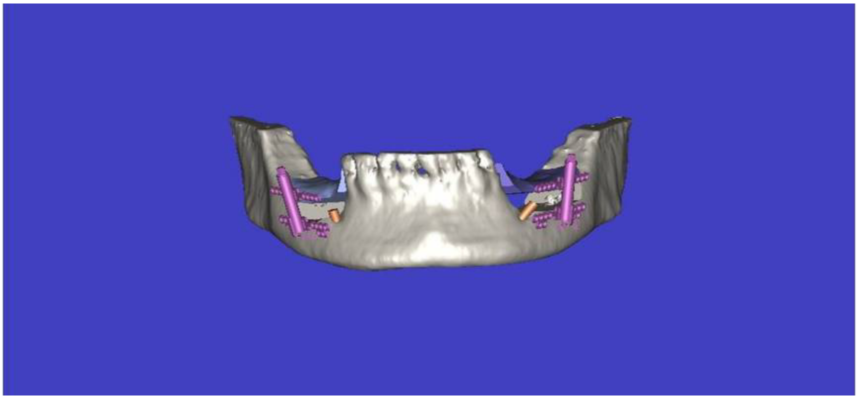


Figure 2: Design of the osteotomy and position of the distraction device

Checking for absence of contacts

Selection of the device

Selection of the sites for screw placement (Fig 3)

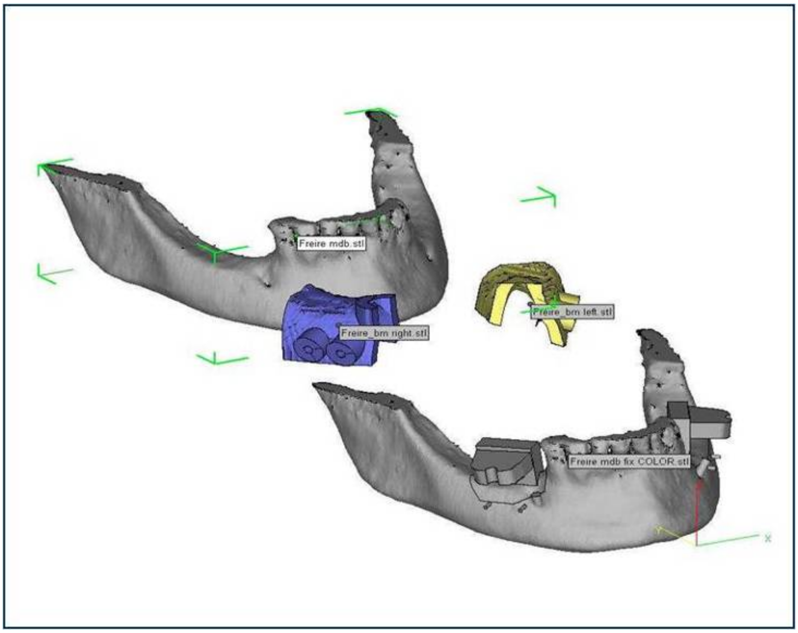
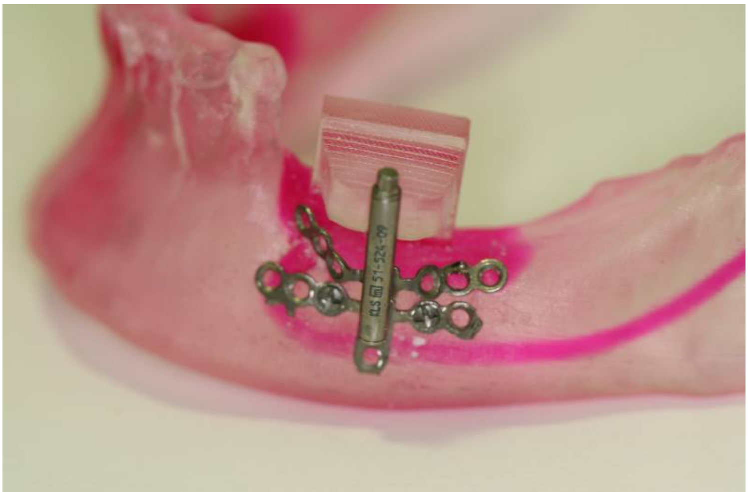


Figure 3: Position of the screws on the mandibular bone

Checking for absence of anatomic collisions or invasion of adjacent structures (Robiony et al, 2008).

Planning of the initial vector of distraction (Kanno et al, 2008; Robiony et al, 2008)

Distractor conformation (size, shape, angulation) for sterilization prior to surgery (Figs 4,5 y 6).



Figures 4, 5 and 6: Planning of the distraction vector and modelling of the device before the surgery

Distractor conformation (size, shape, angulation) for sterilization prior to surgery

Application of techniques for postoperative vector control (direction, length, mesial and distal rest, use of prosthetic and/or orthodontic devices) (Bilbao, 2002; Herford, 2004).

Clinical case

Correction of a post-traumatic defect

A 32 year-old female treated for a maxillomandibular fracture that included the alveolar process by means of interarch fixation with wires. Autogenous bone grafting was also attempted but failed after graft exposure when wearing dental-supported bridgework.

Intraoral exploration and panoramic X-ray reveal an alveolar defect at the maxillary area from the central incisor to the right canine, midline deviation (Fig. 7) and inclination of the occlusal plane. The patient dismisses orthognatic corrections and rejects bone grafting.

Figure 7: Panoramic X-Ray

Decayed teeth with periapical pathology were removed. Osteotomy for the defect region was planned using the SimPlant CMF system (Figs. 8-10) and a 8 mm distraction performed (Figs 11 and 12) by means of a Track Plus distractor (KLS Martin, Tuttinger, Germany). After a twelve-week consolidation period (Figs 13-16), four 4.1x12 mm aesthetic plus dental implants (Straumann AG, Basel, Switzerland) were placed using the submerged technique and transposing palatal connective tissue to augment the thickness of the buccal gingival tissues at the anterior area (Fig 17). Three months later, implants were uncovered using a punch-type scalpel (Fig 18) and an implant supported restoration (Fig 19 and 20) installed (Dr Pazos Carbón).

It is worth to mention that the exposure of the device occurred during the consolidation period (Fig 14) did not entail any inconvenience for the treatment.

Later on, the lip was infiltrated with a long-term resorbable material (Hydrafill® grade III) to gain volume at the areas affected by the scar caused by the initial trauma (Fig 21).

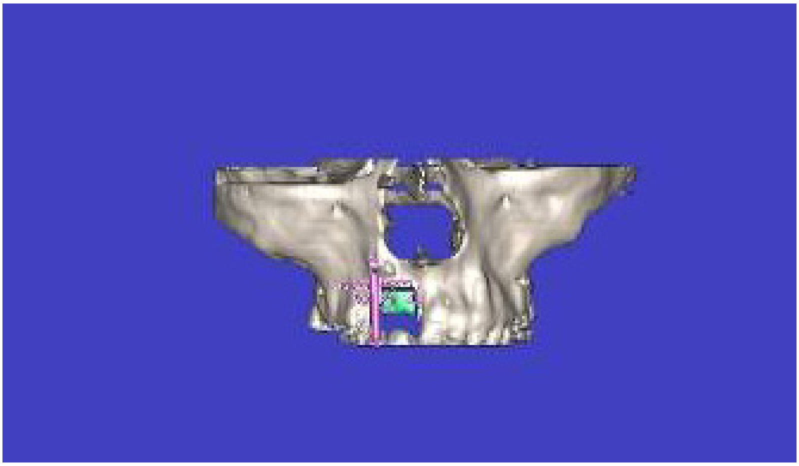


Figure 8: Computadorized planning of the distraction: Frontal view

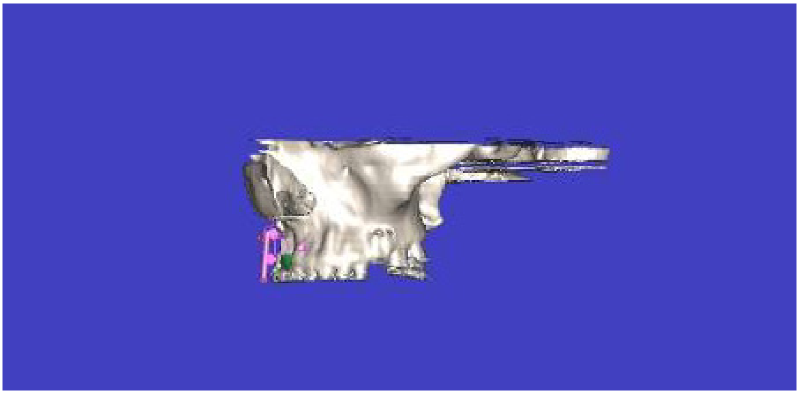


Figure 9: Letral view of the computadorized planning

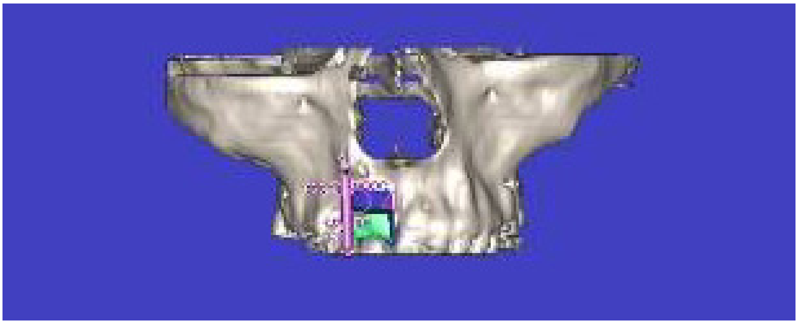


Figure 10: Simulation of the distraction

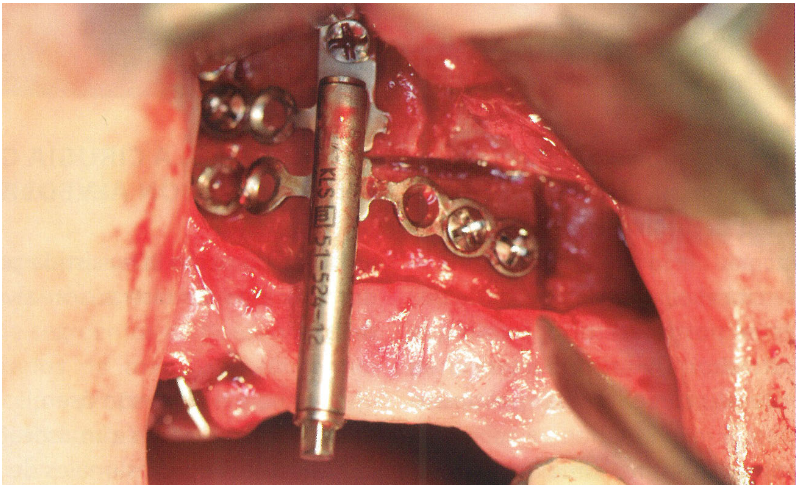


Figure 11: Distractor modeled and screwed in accord with the planning

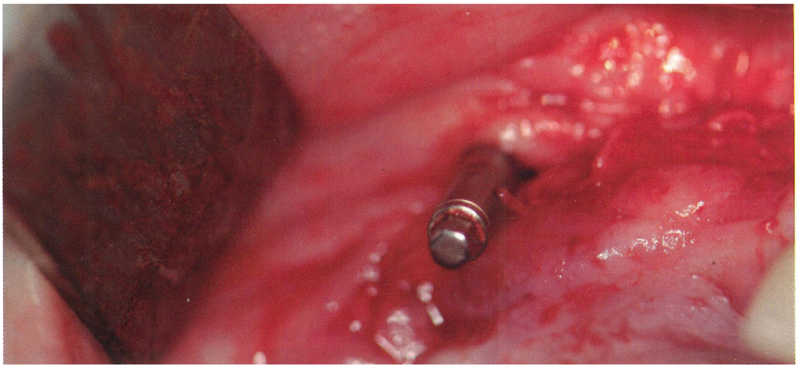


Figure 12. Occlusal view of the distractor.

Figure 13. Panoramic X-Ray contro at the end of the distraction phase and consolidation.

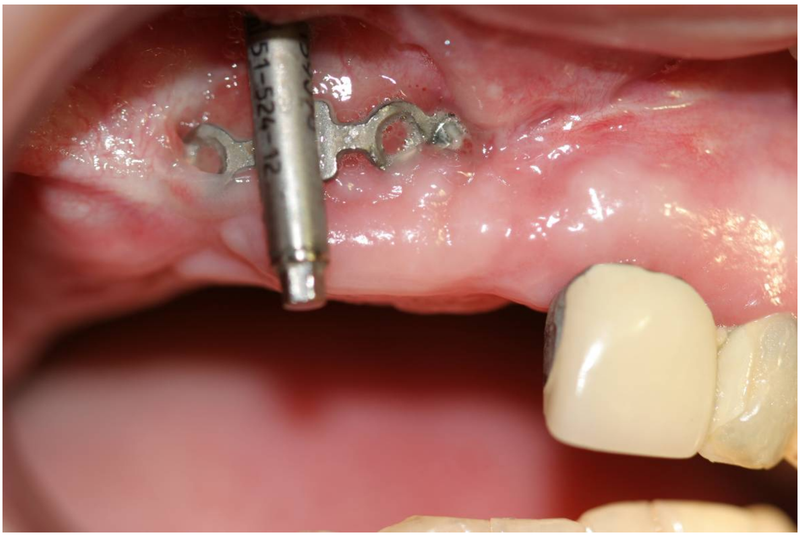


Figure 14: Alveolar process at the end of the reconstruction.

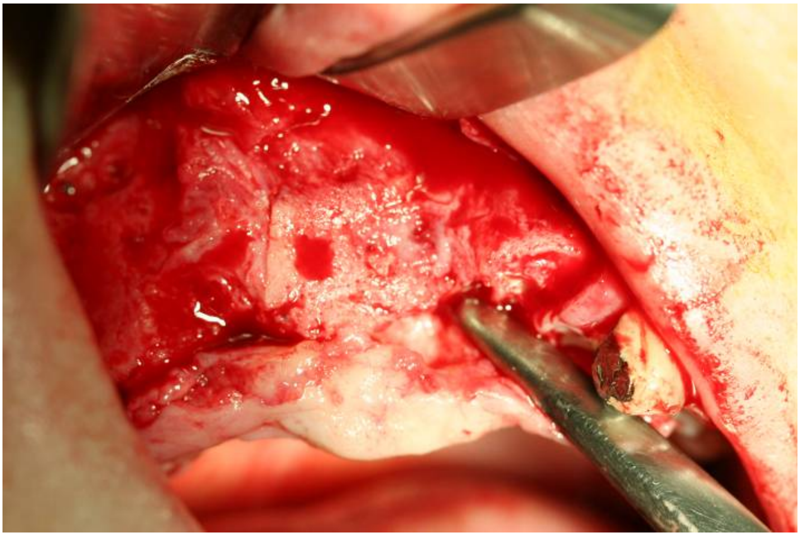


Figure 15: Reconstructed bone by means of alveolar distraction

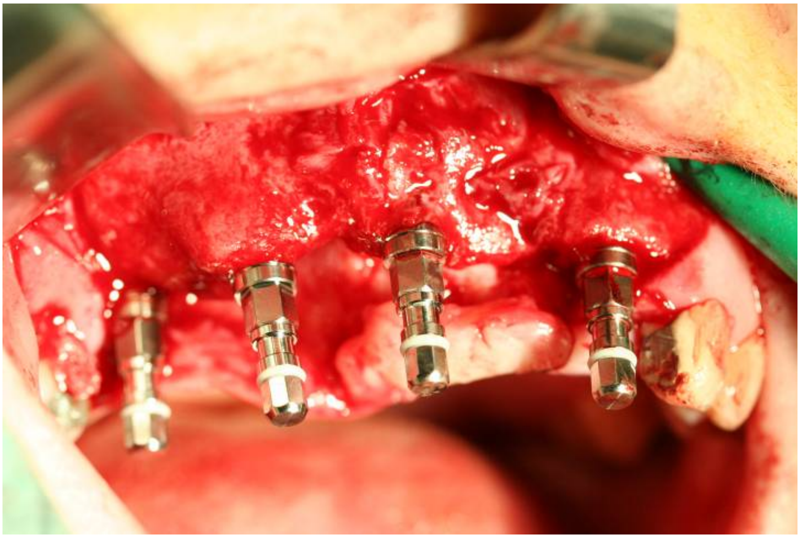


Figure 16. Insertion of four implants

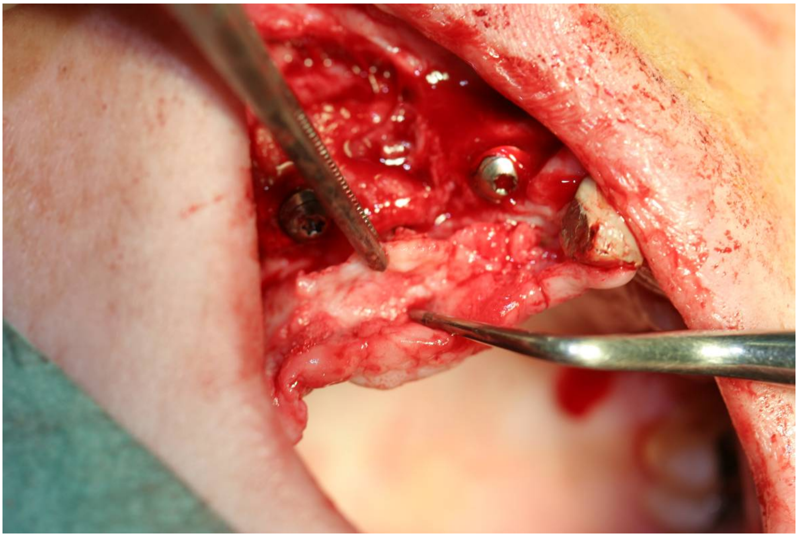


Figure 17: During the second surgery a palatal pedicled connective tissue is made.

Figure 18: The implants after the second surgery using a punch

Figure 19: Final result. Extraoral view.

Figure 20: Final result: Intraoral view

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7

Discussion

7. Discussion

Distraction osteogenesis for alveolar process reconstruction dates back to 1996, and is mostly recommended to increase bone height while improving the soft tissues, which permits the insertion of dental implants in an optimal position. This technique is reported to be efficient for augmenting bone vertically (Esposito et al 2003), being highly predictable (96 – 100% success rate) (Chiapasco et al 2001; Chiapasco et al 2006). However, nowadays, studies on alveolar distraction remain at an experimental stage and are scarce in scientific literature (Cano et al 2006a; Cano et al 2006b).

Although implant survival rate in osseodistraction-generated bone is comparable to that in native bone (Chiapasco et al. 2006, Block et al. 1998, Block et al. 2000, Jensen et al. 2000, Rachmiel et al. 2001), with percentages ranging from 90.4 to 100% (Chiapasco et al 2006), there is not enough scientific evidence to establish individualized protocols for implant insertion that take into account biological or biomechanical factors involved in osseodistraction, such as consolidation time, distractor design, age, gender, anatomical site, bone density and general status of the patient (Cope et al 1999; Cano et al 2006a; Cano et al 2006b).

Despite the accurate knowledge of what levels of primary stability can be obtained in different jawbone regions and what parameters influence these scores (Ostman et al 2006), this factor still impairs implant survival (Stanford 2005). Implant primary stability is largely a mechanical parameter determined bone density, implant design, and surgical technique (Glauser et al 2004). Some additional factors should also be considered when dealing with osseodistraction-generated bone, such as gender (greater stability in males) (Ostman etal 2006; Zix et al 2005) and anatomical site (higher stability in mandible) (Ostman et al 2006; Ersanli et al 2005).

Resonance frequency analysis (RFA) is a non-invasive, highly reproducible method to monitor implant stability (Aparicio et al 2006) which is widely used in clinical research to assess the osseointegration period, immediate load feasibility, and follow-up studies aimed at predicting implant failure (Ernsanli et al 2005; Huang et al 2002). RFA values/ ISQ levels correlate positively with bone quality (Ostman et al. 2006, Bischof et al. 2004, Balshi et al. 2005) and it is conditioned by factors such as bone tissue features, implant sink depth, diameter or type of implant surface (Aparicio et al 2006). These RFA devices need to be calibrated for each implant system separately (Ersanli et al 2005).

The aforesaid parameters together with some others, may influence the assessment of primary stability of implants. In an effort to control for confounding factors, restrictive inclusion criteria were set in a way that only female patients with posterior mandibular implants entered the study. Objective determination of implant stability greatly improves by using a high precision automatic device (Ostell mentor®) with periodic calibrations and repeated measurements. Despite these efforts, and due to the homogeneity of the sample, generalization of the results obtained from the study to other clinical situations should be done with caution.

Metalloproteinase analysis in animal models (sheep) showed that distracted bone was remodelled until 9 months after distraction. Beyond this period, it follows a stable remodelling pattern similar to that of native bone (Marucci et al 2001). Despite these facts, there is a generalised trend amongst clinicians to diminishing this consolidation period to avoid infectious complications, although it is mandatory to keep the distractor in place long enough to obtain a tissue able to bear the biomechanical implications of implant placement (Cano et al 2006a; Cano et al 2006b). In this sense, a three week consolidation period offers an immature bone that starts to form columns form the borders of the distracted area (Nosaka et al 2000), and after three months the cumulative success rate of dental implants was 100% in human models (Chiapasco et al 2001; Chiapasco et al 2006; Rachmiel et al 2001). Human histological studies have demonstrated the presence of bone trabecular parallel to the distraction vector and support the criterion that an 8 week consolidation period is enough for implant placement (Cano et al 2006; Zaffe et al 2002; Raghoebar et al 2002).

The present series, with the same consolidation period, showed a high primary stability which was only slightly lower than that achieved in native bone. ISQ values recorded for both osseodistracted and native bone were well within the limits considered suitable for immediate implant loading, and this consolidation period has granted the maintenance of the regenerated bone without collapse or facture of the area. These results agree with those obtained by Rachmiel who, with identical consolidation period and after a 6-20 follow-up period after osseodistraction, reported a single failure (out of 22 implants) due to improper distracted segment stability (Jensen et al 2000).

Previous reports on native bone using RFA have disclosed a decrease in bone-implant stability in the first month after implant placement (Balshi et al 2005), to increase afterwards in the second and third months, thus suggesting a process of adaptive bone remodelling around the implant (Ersanli et al 2005; Balshi et al 2005). In the present series, and after a 1.5 months osseointegration period, the secondary stability scores were high, with ISQ values slightly over those elicited at implant placement. There also seems to be a better positive linear association in native bone between primary and secondary implant stability.

The results obtained from this series show that after a two-month consolidation period, osseodistracted bone offers a high primary and secondary stabilities after implant placement. Additional advantages of osseodistraction over traditional bone grafting techniques are the absence of a donor area and the simultaneous increase of the soft tissue.

Transport-disc-distraction osteogenesis (TDDO) has been recently recognised as a valuable alternative for mandibular reconstruction after surgical section and radiotherapy, producing functional bone similar to residual bone (Assuntina et al 2007; Seitz et al 2010), with success rates close to 83% in mandibular short case series (González-García & Naval-Gías 2010). However, information available for maxillary reconstruction after radiotherapy is limited perhaps due to the difficulty to obtain an adequate morphology on curved segments –which could make a two-phase distraction mandatory- and to the poor survival rate (59%) reported for maxillary implants inserted after radiotherapy (Visch et al 2002) though studies on this topic are so scarce that no definitive conclusions can be drawn.

The results obtained from the present investigations showed that all six implants inserted in patients who had received maxillary radiotherapy reached a 100% five-year survival rate, despite the protocols followed for their insertion are different from more conservative alternatives (0.5 mm a day and/or twice long consolidation period) reported in the literature (Saulacic et al 2009). These findings –with the inherent limitations to our limited case series- seem to support TDDO as a valuable option for reconstruction of both maxilla and mandible after cancer therapy (including radiotherapy) which may be particularly useful for high-surgical-risk, collaborative patients.

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Conclusions

8. Conclusions

1. The mandibular bone generated by osseodistraction under a protocol of two-month consolidation period (callus maturation) provided such a high primary stability values that would allow immediate implant loading. This finding may permit shortening total treatment time. Moreover, the secondary stability displayed by implants inserted in osseodistraction-generated bone is similar to that recorded for native bone.

2. Osteodistraction and lateral transport procedures carefully undertaken to preserve the periosteum and using piezoelectric devices to obtain an adequate transport disc, together with an active control of the vector, have permitted reconstruction of large segmental maxillofacial bone defects in a pilot study performed in patients after treatment of their cancers (including radiotherapy). These techniques may well be considered a reconstructive alternative to microvascularized flaps.

9

Resumen

9. Resumen

La distracción ósea es un proceso biológico de formación ósea que acontece entre las superficies de segmentos de hueso vital que son separados de manera gradual mediante tracción proceso en el que los tejidos blandos acompañan al hueso en su aumento.

Esta técnica, descrita inicialmente por Codivilla en 1905 y que se comenzó a aplicar a la reconstrucción del proceso alveolar en 1996 por Chin y Block, permite la reconstrucción del proceso alveolar eliminando la necesidad de injertos óseos obteniendo resultados a largo plazo incluso más predecibles en el aumento vertical que los observados utilizando otras técnicas, si bien no existe evidencia científica suficiente para afirmar que sea superior a otras técnicas se considera que para defectos de 6 a 10 mm en el sentido vertical (tipo II según la clasificación de Jensen y Block) puede ser el tratamiento ideal, debiendo considerar el remanente óseo disponible para defectos mayores.

La distracción osteogénica ha visto, desde entonces, como se producía un continuo ir y venir, tanto en la frecuencia, en la indicación de la técnica como en la información que se recoge en la literatura, habiéndose mostrado una tendencia hacia su utilización de una manera más selectiva dado el alto índice de complicaciones que se ha reportado.

Conocemos las bases biológicas en las que se fundamenta la regeneración de tejidos mediante técnicas de distracción, si bien se abren incógnitas acerca de su aplicabilidad clínica.

Por un lado podemos encontrarnos con aquellos casos en los que se necesita una rápida puesta en funcionamiento de la reconstrucción, bien sea por un compromiso estético o por formar parte de una rehabilitación de mayor envergadura. Por otro, nos interesa valorar su aplicabilidad como alternativa reconstructiva en casos en los que tradicionalmente se utilizan técnicas quirúrgicas más agresivas y que exigen una mayor inversión de recursos materiales y humanos obteniendo una adecuada función y una estética que responda a las expectativas del paciente. Tal es el caso de defectos tumorales o traumáticos que habitualmente son reconstruidos con técnicas microquirúrgicas

Es por ello por lo que nos planteamos en este trabajo de Tesis, en primer lugar realizar una puesta al día de la técnica, recogiendo las modificaciones, tendencias, comparaciones con otras opciones de reconstrucción y la prevención y tratamiento de las complicaciones que aparecen en los pacientes.

Si bien parece claro que biológicamente el proceso reparador lleva a la consecución de un hueso de características histomorfométricas, inmunohistoquímicas, radiológicas y densitométricas similares al hueso prístino, es importante conocer cuál es el comportamiento mecánico de ese hueso neoformado y si tiene capacidad de resistir las cargas de forma que se pueda plantear la posibilidad de realizar tratamientos en los que se incluya una puesta en función inmediata o temprana de las fijaciones.

Esto llevaba a la no existencia de un protocolo claro de temporalidad en la colocación de los implantes existiendo referencias a periodos tan cortos como 3 semanas y tan largos como tres meses.

Para ello hemos diseñado un estudio en el que comparamos la estabilidad mecánica de implantes colocados en sector posterior de mandíbula reconstruido con distracción osteogénica y con un periodo de maduración del callo de 8 semanas (N:32) de acuerdo con los estudios histológicos existentes con implantes colocados en los mismos sectores pero sobre hueso prístino (N:39).

Todos los implantes se colocaron en mujeres, eran manufacturados por la misma empresa Straumann (Institut Straumann AG, Basel, Swiyzerland) y de longitud y diámetro (RN 4,1 X10mm).

La estabilidad mecánica del implante se midió en el momento de la colocación de las fijaciones y posteriormente a las 6 semanas , utilizando para ello el análisis de frecuencia de resonancia. Para ello se atornilla al implante un transductor denominado smartpeg que se activa mediante un pulso magnético emitido por la sonda integrada en el sistema, cuyo nombre comercial es Ostell Mentor. De acuerdo a la respuesta a este estímulo se refleja un valor en la sonda que viene expresada en unidades ISQ, que si bien aleatorias, permiten establecer comparaciones entre diferentes implantes o en la evolución de una determinada fijación.

De acuerdo con los resultados, la estabilidad es significativamente mejor, en el momento de la colocación del implante, en el caso de los implantes insertados en hueso prístino, observándose una mejoría en la estabilidad durante el periodo de integración en ambos grupos. Ambos valores se encuentran entre los límites de lo que se considera como ideal en la literatura de cara a la realización de tratamientos con carga inmediata, lo que abre la posibilidad de acortar los tiempos de tratamiento en pacientes sometidos a reconstrucción con distracción osteogénica.

Para poder alcanzar el éxito de este tipo de reconstrucción es fundamental además de una depurada técnica quirúrgica, una planificación no sólo de la línea de osteotomía sino, fundamentalmente del vector de distracción.

Para ello se han diseñado diversos tipos de sistemas de planificación, si bien el que más prometía, vista su aplicabilidad en otros campo de la implantología y la cirugía oral y máxilofacial, era la utilización de programas informáticos de simulación y confección de modelos estereolitográficos. No obstante la experiencia ha mostrado que los factores anatómicos y la dinámica determinada por las múltiples inserciones de la musculatura oral , determinan la obligación de ejercer un control activo del vector tanto durante la fase de distracción como durante la fase de consolidación. Lógicamente, todo esto no tendría ningún sentido sin una aplicabilidad clínica y una serie de ventajas sobre otras técnicas de reconstrucción.

Tradicionalmente la osteodistracción se ha considerado una técnica ventajosa frente a otras opciones de tratamiento por el aumento simultáneo de tejidos duros y blandos, la resistencia a la infección, no precisa donante, la rapidez de resultados superior al de los injertos libres, es más económico que los injertos vascularizados, se puede realizar bajo anestesia local y se produce menor reabsorción del hueso que con otras técnicas

No obstante, la literatura también hace referencia a un alto índice de complicaciones: así, pérdidas de vector (más frecuente en el caso de la utilización de dispositivos intraóseos), fracturas de dispositivo y fracturas óseas.

Además, se añaden las posibles complicaciones inherentes a cualquier cirugía y que son comunes a las de otras técnicas de reconstrucción (edema, hematoma, hemorragia, alteraciones sensitivas, etc.)

Los hallazgos previos permiten sugerir la utilidad de la técnica en la reconstrucción de defectos segmentarios resultantes de la resección tumoral.

Dado que el resultado estético y functional o lo que es lo mismo la calidad de vida resultante en pacientes que han sido sometidos a tratamiento quirúrgico seguido o no de radioterapia está en íntima relación con la reconstrucción tanto del tejido óseo como las partes blandas este objetivo es primordial y más, si es posible, en un solo tiempo.

Para ello el tratamiento aceptado como idóneo es la utilizción de colgajos compuestos microvascularizados. Sin embargo existen casos en los que los pacientes presentan una relación riesgo – beneficio desfavorable que hace necesario plantearse la necesidad de utilizar otras técnicas.

Es en este escenario en el que la distracción osteogénica ha mostrado poder ser una alternativa, más si tenemos en cuenta la posibilidad de aplicación en pacientes radiados, si bien la información es escasa sobre todo en lo concerniente al funcionamiento del complejo implante-hueso.

Nuestra técnica, se llevó a cabo en 4 pacientes, en los que se han realizado resecciones segmentarias seguidas de reconstrucción mediante transporte óseo y distracción osteogénica. (tres casos de carcinoma oral de células escamosas) y uno de condrosarcoma mixoide de maxilar superior y hueso malar.

En la técnica quirúrgica se presto especial atención a la preservación del periostio del fragmento a transformar en disco de transporte de entre 7 y 15 mm, lo que se realizó mediante osteotomía con instrumental pezoeléctrico.

Se realizó una distracción entre mm aplicando tras el period inicial de latencia de seis días le proceso de distracción- contracción con una ratio 3:1. Para disminuir la tension de tejidos blandos y una longitud de movimiento diaria de 0,75 mm..

La distracción consiguió reconstruir defectos de entre 30 y 55 mm y en dos de los casos se completó el tratamiento con radioterapia 60 Gy que sin aplicación de oxígeno hiperbárico, lo que permitió colocar un total de seis implantes sin complicaciones intra postoperatorias o en la evolución que fue de entre tres y nueve años. No se observaron diferencias en la supervivencia de implantes situados en hueso reconstruido sobre tejidos radiados.

Estos hallazgos estarían de acuerdo con la literatura referente a la inserción de implantes osteointegrados en mandíbulas previamente radiadas. Sin embargo, el pronóstico se ensombrece en los casos en los que los implantes se sitúan sobre hueso radiado en el maxilar superior.

La posibilidad de conseguir tejidos adecuados para la inserción de implantes, con menor morbilidad que los injertos microvascularizados y unas características mecánicas y biológicas que no muestran diferencias significativas con el hueso autógeno, hacen pensar que sería posible hacer de esta técnica, un arma útil en el arsenal del cirujano reconstructor.

Como limitación fundamental debemos reseñar la imposibilidad de reconstrucción anatómica de segmentos curvos, lo que se puede solventar en parte realizando un doble proceso de distracción; si bien siempre resultaría una zona intermedia cuya morfología y estructura deben ser modificadas, completadas y reforzadas mediante técnicas de osteotomía, injerto óseo y eventual colocación de material de osteosíntesis.

Finalmente, valoramos la perspectiva de desarrollo de esta técnica utilizando programas informáticos y teniendo en cuenta las peculiaridades de la técnica, en la que interactúa un proceso de regeneración biológico con las tensiones mecánicas ejercidas por las estructura anatómicas circundantes.

Ya en el año 2000 Gaagl presentó un estudio realizado sobre nueve pacientes en los que la planificación para la colocación de implantes distractores se realiza previo estudio de modelos confeccionados a partir de estudios de tomografía axial computadorizada en tres dimensiones tal y como se realiza en cirugía craneofacial, sugiriendo la posibilidad de la aplicación de programas informáticos de simulación y planificación también en la reconstrucción del proceso alveolar mediante técnicas de distracción histogénica.

Posteriormente Kanno presenta su experiencia en la planificación y simulación del tratamiento utilizando el programa SimPlant OMS de Materialise , siendo sus resutados dispares y sometidos a gran variabilidad individual. Es de hacer notar que, si bien somete al distractor utilizado, capaz de establecer un vector determinado en las tres dimensiones del espacio, a la máxima corrección vestibulo lingual, las diferentes resistencias obtenidas en cada individuo hacen prácticamente imposible establecer un protocolo de modelado con aplicabilidad clínica real. A la vista de la escasa bibliografía sobre este tema y de la experiencia clínica generada en este trabajo de Tesis, no parece que exista una predictibilidad basada en el cálculo del vector de distracción utilizando programas de planificación, si bien parecen existir ventajas en la utilización de estas herramientas:

-Permite identificar estructuras anatómicas, como el nervio dentario inferior, el seno maxilar o la fosa nasal, evitando su daño intraoperatorio.

-Nos brinda la posibilidad de planificar la situación exacta del dispositivo distractor, su modelado y esterilización preoperatorios, reduciendo los tiempos quirúrgicos. También, permite el estudio del defecto óseo, la reducción del riesgo de fractura, gracias a una planificación real e incluso palpable del tamaño de los segmentos que van a ser separados mediante la osteotomía quirúrgica. Además, proporciona un canal de comunicación entre profesionales de gran exactitud. Otras posibilidades serían:

-Planificación de los implantes a colocar de acuerdo con la filosofía arriba-abajo.

-La osteotomía puede ser prediseñada, de forma que la utilización de la plantilla creada y su combinación con cirugía con instrumental piezoeléctrico, dotan de rapidez, precisión y seguridad a dicha fase del tratamiento.

-Comprobación de ausencia de contactos entre el disco de distracción y mesial y distal.

-Elección del dispositivo a colocar.

-Determinación de la situación de los tornillos.

-Planificación del vector inicial de distracción

-Conformación del distractor (forma, tamaño, angulación) para su esterilización previa a la cirugía

-Cálculo del aumento de hueso necesario considerando una sobrecorrección del defecto , que según algunos autores puede llegar a ser del 25%

-Aplicación de técnicas de control postoperatorio del vector (dirección, longitud, apoyo en mesial y distal, utilización de elementos de prótesis y/o ortodoncia)

En cualquier caso, el desarrollo de procedimientos de simulación quirúrgica, podría permitir disminuir la morbilidad e incrementar la efectividad clínica del procedimiento.

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11. Papers published from this PhD thesis

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Alveolar Distraction Osteogenesis for Dental Implant Preparation: An Update

Luis G. Vega, DDS[a,*], Arturo Bilbao, MD, PhD[b,c]

KEYWORDS

• Alveolar distraction • Alveolar reconstruction
• Dental implants • Bone grafting

Current standards in implant dentistry are intended to provide natural prosthetic restorations with the finest esthetic and functional outcomes. Several parameters have been suggested to achieve gold-standard results: adequate bone height, width, and anteroposterior projection; adequate soft tissue quantity and quality; preservation of buccal sulcus; and adequate papillae and gingival contour.[1] The preservation and reconstruction of the alveolar bone and surrounding soft tissues for the placement of dental implants has become fundamental in the contemporary practice of oral and maxillofacial surgery. As described elsewhere in this issue, multiple techniques have been used for these purposes.

Since its introduction in 1996,[2] alveolar distraction osteogenesis has been considered a viable technique for reconstruction of alveolar bone before implant placement. In 2004, the *Oral and Maxillofacial Clinics of North America* published an article on alveolar distraction osteogenesis. Batal and Cottrell[3] comprehensively reviewed the history, biologic principles, devices, clinical applications, and surgical techniques in alveolar distraction osteogenesis, and readers are referred to this text for the basic concepts on alveolar distraction. This article discusses newer research and provides clinical advice on the practice of alveolar distraction osteogenesis.

BIOLOGY OF ALVEOLAR DISTRACTION OSTEOGENESIS

Alveolar distraction osteogenesis uses biologic principles described in the orthopedic literature.[4,5] After performing an alveolar bone osteotomy, a distractor device is placed in the transport segment, which remains fully vascularized via its periosteum. Subsequently, the bony segment is subjected to gradual traction that separates it from the basal bone; this traction activates tissue growth and regeneration, forming a distraction callus that progressively matures into bone. The resultant bone mass and shape depends on the vector of distraction, mechanical forces, and the blood supply.

Several biologic processes occur during and after distraction. In recent years, several publications have reported specifically on the biology of human alveolar distraction osteogenesis.[6–11] Chiapasco and colleagues[8] reported that, after 12 weeks of consolidation, the percentage of mineralized bone that formed in the distracted

[a] Division of Oral & Maxillofacial Surgery, Department of Surgery, Health Science Center at Jacksonville, University of Florida, 653-1 West 8th Street, Jacksonville, FL 32209, USA
[b] Santiago de Compostela University Hospital, Travesía da Choupana s/n, 15706 Santiago de Compostela, La Coruña, Spain
[c] Private Practice, La Rosaleda Hospital Policlínico, Santiago León de Caracas, 1, 15701 Santiago de Compostela, La Coruña, Spain
* Corresponding author.
E-mail address: luis.vega@jax.ufl.edu

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region ranged from 21.6% to 57.8%. The newly formed bone was oriented perpendicular to the osteotomy cut and consisted of woven bone reinforced by parallel-fibered bone. Türker and colleagues[10] reported similar histologic findings after 12 weeks of consolidation. They also correlated those findings with panoramic radiographs, dental computed tomography (CT) scans, and bone density analysis. Panoramic radiographs at the end of distraction showed radiolucent gaps; after 12 weeks the distraction gaps appeared to be mostly radio-opaque with some radiolucent areas, and after 1 year the appearances were the same as the preexisting bone. Dental CT scans taken 12 weeks after distraction confirmed the increase of alveolar heights and filling of the distraction chamber; after 1 year the CT scans showed formation of bone that appeared similar to preexisting bone. Bone density analysis from the dental CT showed that the newly formed bone after 12 weeks of consolidation was denser than medullary bone. Iizuka and colleagues[6] found that a bidirectional alveolar distractor formed high-density new bone with complex architecture. The new bone was oriented in several different layers. They concluded that the favorable bone regeneration was achieved as a result of the combination of slow distraction and gradual anterior angulation.

Consolo and colleagues[7] compared the use of traditional alveolar distraction with an intermittent loading alveolar distraction. After reaching the distraction goal, the individual started an activation-deactivation protocol for 8 weeks during the consolidation phase. The histologic results at 6, 8, and 12 weeks of consolidation showed evidence of early bone formation with superior structure quality.

Adequate blood supply is crucial for the development, remodeling, and regeneration of bone. Amir and colleagues[9] found a positive correlation between blood vessel volume and bone volume density in newly formed bone after alveolar distraction. This finding supports the concept that vascularity is necessary for the formation of new bone.

Lindeboom and colleagues[11] reported on the vascular density changes in oral mucosa after alveolar distraction. They showed that the main increase of vascularity was during the activation phase. The vessel density during consolidation was comparable with preoperative levels.

DISTRACTION PROTOCOL

After almost 15 years of widespread use, there is still controversy regarding the best protocol. As new devices and applications have been designed, different distraction protocols have been tested and established. However, the original clinical phases of distraction remain the same: osteotomy, latency, distraction, and consolidation (Fig. 1).

Osteotomy

Osteotomy has traditionally been performed with rotary burs, different kinds of saws, and osteotomes. Piezosurgery for alveolar distraction osteotomies has also been reported in the literature.[12,13] By comparing piezoelectric with conventional osteotomies for alveolar distraction, González-García and colleagues[13] found that the surgical difficulty and the incidence of intraoperative complications were significantly lower in the piezoelectric group. Their results showed that the postdistraction alveolar morphology was worse in the piezoelectric group. They theorize that the piezoelectric osteotomies will create a wider initial gap that may favor the appearance of granulation tissue without good osteogenic potential.

Latency Period

Latency period is defined as time from surgery to the beginning of distraction. In an alveolar distraction systematic review from 1996 to 2006, the most common latency period was 7 days (66% of the cases reviewed) to allow for healing of the mucoperiosteum and reduce the risk of wound

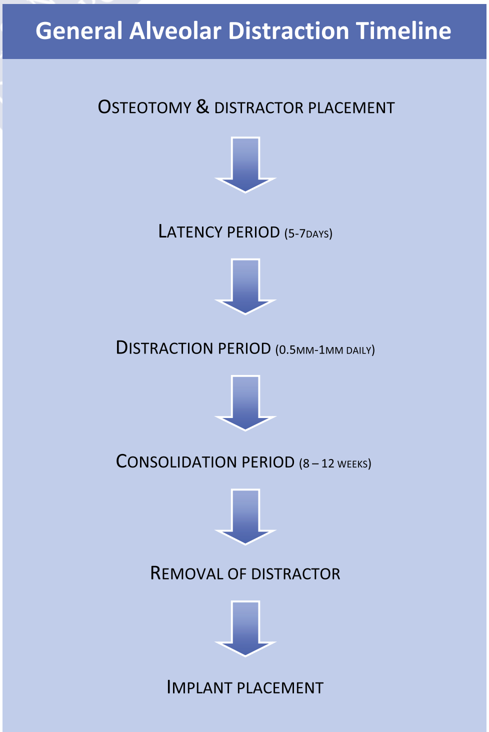

Fig. 1. General alveolar distraction timeline.

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dehiscence. Extended latency periods of more than 15 days were applied to ensure complete revascularization of the transport segment in cases in which the mucoperiosteal pedicle is small or endangered.[14]

Distraction Period

The distraction period encompasses the time between initial activation and end of the activation of the distractor device. The amount of distraction required is generally based on the amount of tissue necessary to fulfill the implant and dental rehabilitation goals. Several studies have focused on the amount of alveolar distraction relapse, and their recommendation is to overcorrect by 20% to 25%.[15,16] Apart from the amount of distraction needed, the distraction rate and rhythm are of paramount importance during this period.

Distraction rate

The daily amount of bone to be distracted is known as distraction rate. Saulacic and colleagues[14] reported in a systematic review that the mean distraction rate was 0.71 (±0.27) mm. They also noted a lower distraction rate of 0.4 to 0.5 mm in cases in which distractor implants and horizontal distraction were used. According to Amir and colleagues,[17] a distraction rate of 0.5 mm per day results in faster osteogenesis than a distraction rate of 1 mm in elderly patients.

Distraction rhythm

Distraction rhythm is the number of distraction activations per day. According to Saulacic and colleagues,[14] the rhythm in alveolar distraction has tended to be chosen empirically, in part because of a lack of experimental findings. They reviewed 209 distractions in 197 patients, and found that the rhythm of distraction ranged between 1 (62%), 2 (35%), and 4 times daily (3%).

Consolidation Period

This is the period that allows for maturation and corticalization of the regenerated bone. According to Amir and colleagues,[9] a minimum of 10 weeks is required for new bone to bridge a 10 mm alveolar distraction gap. It has been suggested that the poorly mineralized bone tissue found after 10 weeks of consolidation will start an adaptive response that would increase the bone matrix mineralization with placement of dental implants.[18] A systematic review found that the mean consolidation period was 12.22 (±5.58) weeks. A difference was noted in the consolidation period when different distractor devices were used. The mean consolidation period on intraosseous distractors was 8.82 (±2.67) weeks, 11.44 (±2.55) weeks for the extraosseous distractors, and 18.02 (±3.50) weeks before prosthetic treatment started in distraction implants.

ALVEOLAR DISTRACTION DEVICES

Novel alveolar distraction designs are constantly being developed for research and clinical purposes. As a general rule they have been classified as intraosseous and extraosseous, depending on the placement in relation to the bone. In a study comparing clinical outcomes of intraosseous and extraosseous alveolar distractors, Uckan and colleagues,[19] found no significant statistical difference despite the higher complication rate and lower implant success in the intraosseous group. Devices can also be categorized as unidirectional and multidirectional, depending on the direction of the movement. Initial alveolar distractor designs allowed for only a unidirectional movement, making correct positioning of the device and vector control most important. Recent publications have shown the clinical value of multi directional alveolar distraction devices.[6,20,21] A retrospective study comparing outcomes of unidirectional and bidirectional distractor devices, Schleier and colleagues[21] found no significant statistical differences in the bone gain or implant success. Moreover, several cases with unidirectional distraction had to be bone grafted at the time of implant placement. They concluded that this difference was caused by the precise control of the distraction process in the bidirectional distraction group.

INDICATIONS FOR ALVEOLAR DISTRACTION OSTEOGENESIS

Several clinical indications for alveolar distraction osteogenesis have been reported in the literature (**Box 1**).[22–24] Alveolar reconstruction in preparation for dental implant placement continues to be the

Box 1
General applications for alveolar distraction osteogenesis

- Moderate to severe vertical alveolar bone defects
- Segmental deficiencies of the alveolar ridge
- Narrow alveolar ridges
- Adjuvant to other bone graft techniques
- Gradual vertical movement of ankylosed teeth
- Gradual vertical movement of an osseointegrated implant together with the surrounding alveolar bone

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most common indication (**Fig. 2**). Reconstruction efforts have used alveolar distraction as a definitive procedure to establish the ideal alveolar ridge or as an adjunctive procedure used to gain bone as part of a larger reconstruction plan. Overall, alveolar distraction offers several advantages compared with other augmentation techniques (**Boxes 2** and **3**).[25]

Alveolar distraction has traditionally been used for vertical augmentation of the alveolar ridge, but horizontal[26–28] and segmental alveolar distraction[29,30] have also been described. The main indication for alveolar distraction is to manage the vertical defects in the anterior maxilla and mandible. Posterior maxillary defects are best addressed with traditional techniques such as sinus lift or bone grafts. Vertical defects of the posterior mandible can be treated with alveolar distraction but, if the defect also has a horizontal component, a more traditional approach with an onlay bone graft or guided tissue regeneration is recommended.[31,32]

To facilitate the evaluation and treatment of vertical alveolar defects, Jensen and Block[33] proposed a classification system in which they defined a class I defect as a mild alveolar vertical

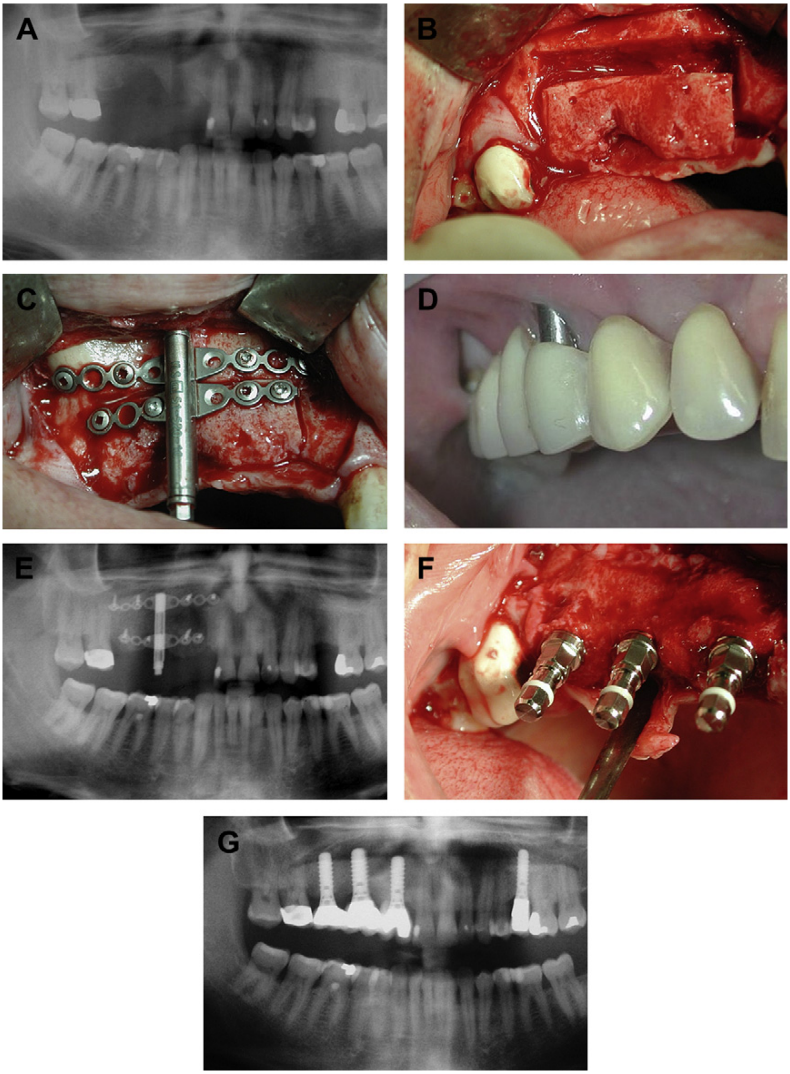

Fig. 2. Alveolar reconstruction using alveolar distraction in preparation for dental implants. (*A*) Right maxillary posttraumatic vertical defect. (*B*) Osteotomy. (*C*) Alveolar distractor in place. (*D*) Vector control using a prosthesis. (*E*) Panoramic radiograph after the end of the distraction. (*F*) Placement of dental implants. (*G*) Panoramic radiograph at the end of the treatment.

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Box 2
Advantages of alveolar distraction osteogenesis for preparation for implant placement

- Simple technique
- Simultaneous augmentation of bone and soft tissues
- Less resorption than traditional bone grafts
- Transport segment can include teeth or implants, facilitating the correction of occlusal or prosthetic defects
- Elimination of donor-site morbidity
- Shorter treatment times compared with traditional bone grafting techniques
- Allows the implementation of complementary techniques when results are not optimal

deficiency with up to 5 mm that ideally can be treated by a sandwich osteotomy or more traditional bone graft techniques, although distraction can be considered when there are prosthetic concerns in the esthetic zone. Class II defects consist of a moderate vertical loss of 6 to 10 mm that ideally will benefit from alveolar distraction. Class III defects are severe vertical losses greater than 10 mm. Treatment of these defects depends on the available bone stock. If sufficient bone exists, distraction can be carried out first, and definitive alveolar bone form and position can be performed with a bone graft. If the amount of bone is not sufficient for distraction, bone augmentation is carried out first followed by distraction. Vertical defects that involve adjacent teeth with significant bone loss are designated as class IV. In these cases, by extracting the affected dentition, the defect will be converted into a class II or III defect, making the problem more predictable and easier to resolve.

PLANNING FOR ALVEOLAR DISTRACTION OSTEOGENESIS

Clinical examination will establish a preliminary idea of the patient prosthetic needs, occlusion, and the size and shape of the alveolar defect. Maxillary and mandibular models with a diagnostic wax-up will allow corroboration of the clinical findings. They can also be used to fabricate a surgical splint that could be use for vector control as well as temporary restoration. Models also play an important role in planning for the distraction vector, allowing preadaptation of the device, decreasing surgical time, and identifying possible device interferences with opposing dentition. In more complex cases, sterolithographic models are a good option for treatment planning.

Radiographic examination with plain films or CT scan is useful for alveolar defect assessment but it also allows for planning the length and height of the osteotomy. Of great importance is the amount of bone stock and its relationship with the inferior alveolar nerve, inferior border of the mandible, nasal floor, and maxillary sinus. These factors could limit device placement or the distraction procedure. Added consideration should be given to the prophylactic plating of the mandible in which the remaining basal bone is scarce, to prevent fracture and retention of compromised teeth adjacent to the distractor procedure and to help with vector control. Newer technologies, such as computer-assisted surgical planning, are also being applied to alveolar distraction (**Fig. 3**).[34]

Box 3
Disadvantages of alveolar distraction osteogenesis for preparation for implant placement

- Patient acceptance and compliance
- Requires careful vector control
- Interference with occlusion might require the construction of protective appliances
- High device cost

ALVEOLAR DISTRACTION: SURGICAL ADVICE

During the different phases of alveolar distraction, there are a series of considerations that can contribute to a successful outcome. Allocating sufficient time for surgical planning is probably the single most important element in alveolar distraction.

Incision

- Special consideration should be given to the location of the incision, because it will affect the quality of the soft tissue that will be augmented at the end of treatment
- Use sound surgical principles that will guarantee proper blood supply to the mucosa and bone
- Careful and conservative dissection will maintain the vascularity of the transport segment, decreasing excessive resorption and avoiding damage to adjacent structures.

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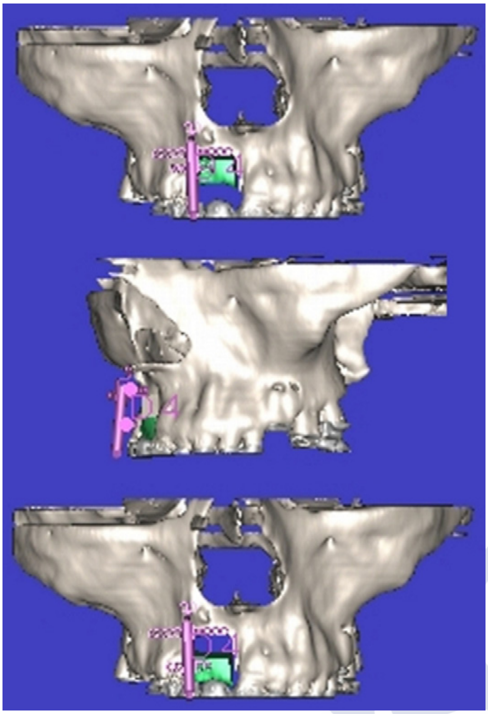

Fig. 3. Alveolar distraction treatment planning using computer-assisted surgical software.

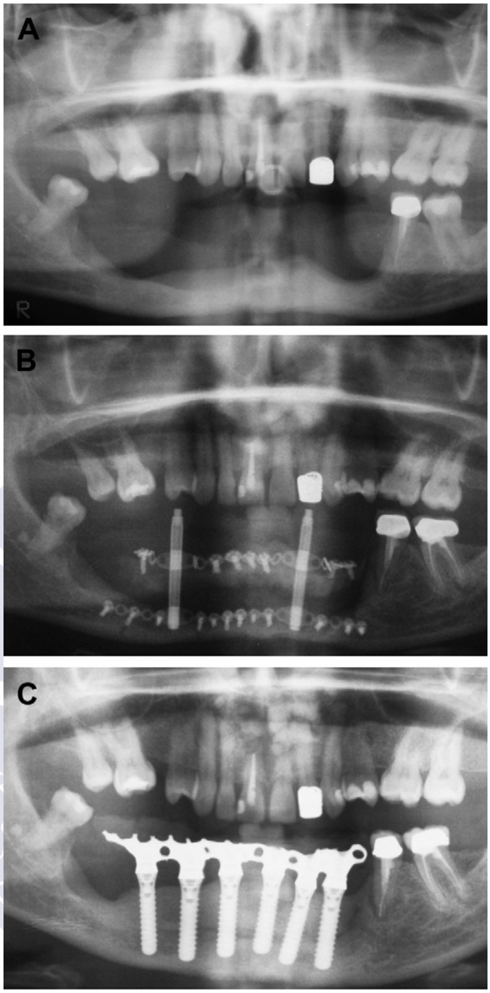

Fig. 4. Placement of 2 distractors for large transport segments. (*A*) Large mandibular defect. (*B*) Placement of 2 distractors. (*C*) Final result after distraction and implant placement.

Osteotomy and Distractor Placement

- Use a trapezoidal, semielliptical, or L-shaped osteotomy, depending on location
- Lingually convergent osteotomies will decrease the lingual tipping of the distractor
- A piezoelectric-assisted osteotomy will allow a deeper cut, decreasing the amount of chiseling required
- A transport segment as large as possible (avoiding compromise of basal bone and adjacent structures), and not just containing cortical bone, will avoid a higher rate of resorption
- Newer modular extraosseous distractors will allow the osteotomy to be performed after the placement of the device, because of their ability to remove the distractor rod
- Check that the transport segment is able to move freely through the extension of the distractor (with the exception of L-shaped osteotomy)
- In cases of large transport segments, consider the placement of 2 distraction devices (**Fig. 4**)
- During extraosseous distraction, vector control can be achieved if the distractor plate for the transport bone is cut longer than usual, allowing movement along the buccal bone surface.

Distraction Phase

- Decreasing the distraction rate and maintaining good oral hygiene will help in the treatment of wound dehiscence.
- Patients should carry a daily log to record the amount of daily activations.
- Monitor the distraction vector carefully. Several methods for vector control have been described,[35–38] and these are illustrated in **Fig. 5** and **Box 4**.

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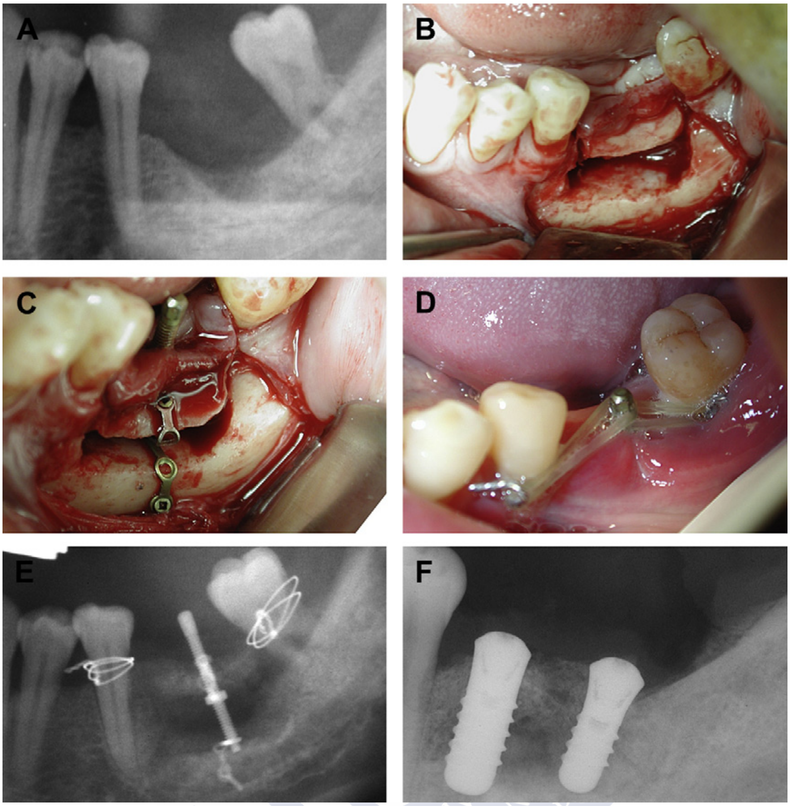

Fig. 5. Vector control. (*A*) Mandibular vertical defect with severe bone loss involving second molar. (*B*) Osteotomy. (*C*) Placement of intraosseous distractor. (*D*, *E*) Vector control using orthodontic elastics and compromised tooth. (*F*) Final result after distraction, extraction of second mandibular molar, and placement of 2 implants.

- When a prosthesis is used as vector control, it must be adjusted daily.
- Always consider overcorrection.

Consolidation Phase

- Covering the distractor rod with a red Robinson catheter will avoid excessive trauma to the surrounding soft tissues

Box 4
Methods for vector control in alveolar distraction osteogenesis

- Device modifications
- Orthodontic mechanics: elastic traction, wire stabilization
- Modified prosthesis
- Manual manipulation of the regenerated bone
- Osteotomy after distraction completed

- Avoid excessive pressure on transport segment when using a temporary prosthesis
- In selected cases, implant placement during the consolidation phase will allow for stability of the regenerated bone and maintenance of the distraction vector.

Implant Placement

- Thoroughly clean the granulation tissue in the area where an intraosseous distractor has been placed. Avoid placement of implants in this area but, if necessary, use a large-diameter implant
- When possible, use long implants that will engage the native bone. Implant planning software is helpful in this treatment stage
- To avoid further resorption, do not delay implant loading more than traditional implant protocols.

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CLINICAL OUTCOMES IN ALVEOLAR DISTRACTION OSTEOGENESIS

Vertical Bone Gain

Data of 181 patients from a recent review by Chiapasco and colleagues[39] showed that the amount of bone gain after distraction osteogenesis had a range of 3 to 20 mm. Saulacic and colleagues[14] reported in their systematic review the mean bone gain obtained by different types of distractors: distraction implants, 5.02 (±0.09) mm; intraosseous distractors, 7.86 (±0.36) mm; and extraosseous distractors, 9.31 (±0.45) mm. A clinical assessment of 40 patients subjected to an extraosseous distraction showed that the bone augmentation average was 9.5 mm in height, showing a 92.5% success rate.[40] Kanno and colleagues[16] reported comparable results on bone gain using extraosseous distractors; they also noted that, during the consolidation period, there was 15% to 25% bone height reduction. These findings are similar to the previous reports in the literature that recommend 20% to 25% overcorrection in vertical alveolar distraction.[15,41,42] Perdijk and colleagues[43] pointed out the influence of vector of distraction on vertical gain. They studied 34 cases of alveolar distraction on atrophic mandible in which nearly all patients had lingual tipping of the segment by a mean of 12°. This finding meant that, in those cases, only 87% of maximum vertical bone gain could be achieved.

Alveolar Distraction Compared with Conventional Bone Grafting Techniques

In 2004, Chiapasco and colleagues[44] compared alveolar distraction osteogenesis with guided bone regeneration on vertically deficient alveolar ridges. This prospective study evaluated parameters such as bone resorption of the regenerated ridges before and after implant placement, peri-implant bone loss at 1, 2, and 3 years after prosthetic loading of the implant, and success rates of implants. The results suggested that alveolar distraction might offer more predictable long-term results for bone gain maintenance and peri-implant bone resorption. Furthermore, implant success rates were significantly higher in the alveolar distraction group. Chiapasco and colleagues[45] also compared alveolar osteogenesis with autogenous onlay bone grafts using the similar parameters. This study found that bone resorption before implant placement was significantly higher in the autogenous onlay bone graft group. For implant success, no difference was encountered between the groups. Uckan and colleagues[46] also compared alveolar distraction with autogenous onlay graft using complication and implant survival rates. Their results showed a higher complication rate with the alveolar distraction (66.8% vs 33.8%). But they also reported that those complications were minor and easier to treat than those of the autogenous onlay graft. Again, implant survival rates were similar between the groups (91.4% alveolar distraction vs 93.7% autogenous onlay graft). In a prospective study comparing alveolar distraction with inlay bone grafting in the posterior mandible, Bianchi and colleagues[47] showed that, although the mean bone gain with alveolar distraction was significantly better (10 mm vs 5.8 mm), the complication rate was significantly higher in the alveolar distraction group (60%) than in the inlay bone graft group (14.3%).

Two literature reviews of bone augmentation procedures on edentulous ridges for dental implants concluded that it is difficult to demonstrate that one surgical procedure offered better outcomes than another because of the poor methodological quality of the articles published (**Table 1**).[39,48] Their recommendation is to give

Table 1
Comparison of augmentation techniques on edentulous ridges for dental implant placement

Technique	Success Rate (%)	Implant Survival (%)
Guided bone regeneration	60–100	92–100
Onlay bone grafts	92–100	60–100
Split ridge	98–100	91–97.3
Alveolar distraction	96.7–100	90.4–100
Microvascular flaps	87.5	88.2

Data from Chiapasco M, Zaniboni M, Boisco M. Augmentation procedures for the rehabilitation of deficient edentulous ridges with oral implants. Clin Oral Implants Res 2006;17(Suppl 2):136–59.

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priority to those procedures that are simpler, less invasive, involve less risk of complications, and reach their goals in the shortest time.

Alveolar Distraction on a Previously Reconstructed Site

Reconstruction of severe maxillary and mandibular defects for dental implants after trauma or tumor ablation is often a difficult task. Case reports in the literature describe the use of alveolar distraction as adjuvant to enhance sites previously reconstructed with iliac bone grafts,[49,50] scapula free flaps,[51,52] and fibular free flaps.[53,54]

In a retrospective study, Kunkel and colleagues[50] reported on 4 patients who underwent iliac crest bone graft for mandibular reconstruction after tumor ablation and later alveolar distraction with an intraosseous device. The vertical gain range was from 5 to 9 mm and, of the 12 implants placed, 1 failed and 1 had critical bone loss after 40 months of follow-up. Hirota and colleagues[51,52] described the use alveolar distraction to enhance the mandibular reconstruction carried out with free scapula flaps in 2 patients. They reported vertical gains of 9 and 10 mm and placement of 9 implants with a 100% success rate after 2 years of follow-up. In 2009, Lizio and colleagues[54] used alveolar distraction to increase the vertical bone height on 6 patients after reconstruction with free fibula flaps. The mean vertical bone gain was 14 mm (12–15 mm). They placed 35 implants, 4 of which failed during the follow-up period, bringing the cumulative implant survival to 89%. They also reported 1 case with fracture of the remaining basal fibula during consolidation.

Success of Dental Implants in Distracted Bone

Prosthetic rehabilitation facilitated by the placement of dental implants is the ultimate goal of alveolar distraction. Controversy still remains regarding the best time for implant placement.

A prospective multicenter study reported the outcomes of 138 implants placed in distracted bone after 2 or 3 months of consolidation. After a mean follow-up of 34 months after prosthetic loading, the success rate was 94.2% with a cumulative survival rate of 100%. No statistically significant differences were found between the different centers.[55]

Using 92 distractor implants on 46 patients with severely atrophic mandibles, Raghoebar and colleagues[56] reported a survival rate of 97% after a minimum of 62 months of follow-up. In a retrospective study, Elo and colleagues[57] compared the implant success rates in distracted bone with autogenous bone-grafted sites. They placed 184 implants on 65 patients reconstructed with autogenous bone, with an implant success rate of 97%. The distraction group contained 56 implants on 17 patients and a success rate of 98%. Again, no statistical difference was noted between groups.

A systematic review on alveolar distraction analyzed a total of 469 implants placed in distracted bone. The mean osseointegration period was 4.59 (±1.34) months. The overall survival rate was 97%. They reported 14 implant failures, 10 of them before loading. The mean follow-up was 14.19 (±11.03) months. This analysis also found no significant difference in implant failure rate associated with location, indication for distraction, latency period, and daily rate and rhythm. The mean augmentation rates approached a statistically significant difference: rate on successful implants was 6.79 (±2.51) mm and 8.40 (±2.31) mm on failed implants. A significant difference was encountered in the relationship between implant failures and distraction implants. Consolidation period also showed significant differences; failed implants were placed after 8.10 (±2.51) weeks, compared with 12.43 (±5.62) weeks for successful implants. Peri-implant bone level was reported for 301 implants. Stable peri-implant bone level was maintained in 285 (95%) of the implants.[14] Recent studies reported peri-implant bone loss values of 0.89 to 1.9 mm/y in areas of alveolar bone distraction.[42,58]

Immediate Loading of Implants on Distracted Bone

In 2004, Degidi and colleagues[59] presented a case of immediate loading of implants placed in distracted bone. Although this practice has not been popular, a study was carried out comparing data from radiofrequency analysis on implants placed in native bone and distracted bone. Even when the results were significantly inferior for implants placed in distracted bone, the investigators concluded that the values obtained suggest the possibility of immediate loading with outcomes similar to those of implants in native bone.[60]

Adjunctive Techniques to Improve the Outcomes of Alveolar Distraction

Research is being conducted on ways to improve the outcome of alveolar distraction. Robiony and colleagues[61] reported on their long-term experience with 12 patients after alveolar distraction and a combination of autologous bone graft with platelet-rich plasma on severely atrophic mandibles. After performing an osteotomy, the distractor

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Table 2
Complications of alveolar distraction, possible causes, management and prevention

Phase	Complication	Causes	Management	Prevention
Intraoperative	Inability to mobilize the transport segment	• Incomplete osteotomy • Poor osteotomy design with lack of divergence	Retrace osteotomy	Better execution and planning of the osteotomy
	Fracture of the transport segment	• Lack of sufficient bone stock • Excessive force during mobilization of the osteotomy	Small fractures: removal of fragment, relocate distractor arms to new position (extraosseous devices) (**Fig. 6**) Large fractures: suspension of distraction procedure, osteosynthesis, possible bone graft (**Fig. 7**)	Cautious osteotomy and mobilization of the transport segment
	Fracture of the basal bone	• Lack of sufficient bone stock • Excessive force during mobilization of the osteotomy	Reduction and fixation of fracture segments	Careful planification and execution of osteotomy
	Occlusal interference of distractor rod	• Lack of proper planification	Shortening or reposition of distractor rod	Careful planning using cast models
	Damage to adjacent structures	• Improper surgical technique	Conservative	Careful planning and execution of osteotomy
	Distractor fracture (extraosseous devices)	• Excessive bending of distractor arms	Change distractor device	Use cast models to prebend device avoiding excessive manipulation

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During distraction and consolidation	Wound dehiscence	• Excessive tension at closure • Poor soft-tissue coverage	Reduction distraction rate, secondary suture	Smaller distraction rate
	Mucosa perforation	• Sharp bony edges in the transport segment	Trimming sharp edge	Smoothing alveolar ridge irregularities
	Premature consolidation	• Lack of compliance of the patient • Excessive latency period • Slow distraction rate	Repeat osteotomy	Correct patient selection and patient education Decrease latency period Increase distraction rate
	Distractor failure	• Loosening due to poor bone quality on the transport segment • Distractor fracture	Distractor removal Consider distractor replacement or bone grafting procedure (**Fig. 8**)	Avoid excessive manipulation of devices
	Incorrect distraction vector	• Excessive pull from lingual and palatal periosteum, muscle insertions • Incorrect placement of the distractor	Vector control (see **Table 1**)	Careful planning, close monitoring
	Transport bone resorption	• Interruption of blood supply due to excessive reflection of perforation of tissue	Consider overcorrection	Conservative
After distraction	Bone defect	• Multifactorial	Consider bone grafting	Good alveolar distraction technique

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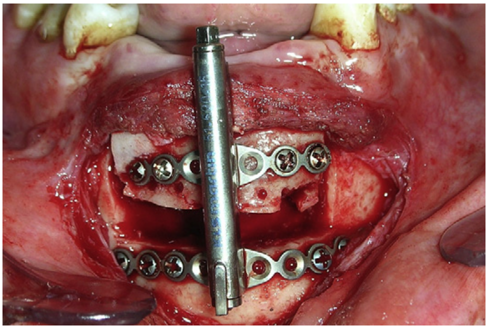

Fig. 6. Small fracture of transport segment treated by repositioning the distractor device.

was activated for 2 to 3 mm and the gap was filled with the combination of iliac crest bone graft and platelet-rich plasma. Their results showed a vertical bone gain that range from 7 to 10 mm with 1 failed case due to scar retraction. The mean decrease of total bone volume was 2.3% at the time of implant placement. A total of 47 implants were placed, and bone loss after 1 year of loading was 0.61 mm and 1.51 mm after 5 years. The implant survival and success rates were 97.9% and 91.5%. A double-blinded trial investigated whether low-intensity pulsed ultrasound therapy stimulates osteogenesis in mandibular alveolar distraction. Biopsies taken at implant placement after 46 $\pm$ 8.1 days of consolidation underwent histologic and microradiographic examination. The investigators concluded that ultrasound treatment does not seem to stimulate bone formation.[62] Dergin and colleagues[63] reported a case using a novel technique whereby alveolar distraction was done incorporating a polytetrafloroethylene membrane for protection of the distraction chamber. No defects were noted in the 10 mm of newly regenerated bone. Further research is necessary to validate this technique. At the time of this writing, no human studies using bone morphogenic proteins and alveolar distraction have been published in the English literature.

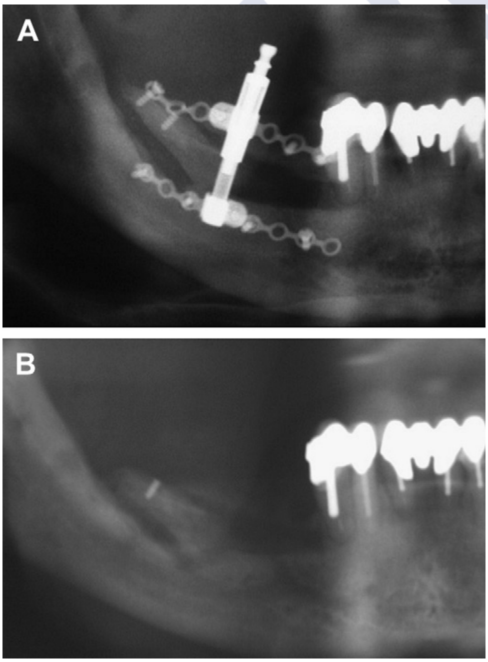

Fig. 7. (*A, B*) Panoramic radiographs showing large fracture of transport segment that required the suspension of the procedure.

Patient Perception and Satisfaction After Alveolar Distraction

Even when objective clinical data suggest good results, ultimately it is patient satisfaction that leads to the success of a treatment plan. Using a distractor implant on 46 patients, Raghoebar and colleagues[56] reported patient satisfaction of 8.1 ($\pm$1.2) (0 = completely dissatisfied; 10 = completely satisfied) after finalization of the prosthetic treatment. Allais and colleagues[64] used extraosseous devices in 50 patients to evaluate the patients' perceptions during and after alveolar distraction. Their findings showed that, in 76% of the cases, the patient reported the surgery as good and bearable (all patients were orally sedated with 15 mg of midazolam). During distraction, 4% of the patients felt pain, 46% had some difficulty activating the device, and 10% needed extra help. The activation rod was a cause of complaint in 52%. Of the 50 patients, 27 had to undergo additional autologous bone grafting, and 70% of them stated that the bone grafting procedure was more painful than the alveolar distraction. Seventy-eight percent of the patients treated with alveolar distraction would undergo this procedure again if necessary. In a more recent study from the French literature, Castry and colleagues[65] analyzed the answers of 23 patients after alveolar distraction. They found that 87% of the patients adjusted well to the procedure. Light to moderate pain was reported by 57%, and 43% of the patients cataloged the procedure as painful. Fifty-seven percent of the patients managed to forget the presence of the distractor, and 65% had no problem with the length of the treatment. Approximately 91% of the patients were able to activate the distractor device on their own, and 52% of the patients reported that they would undergo another distraction procedure if necessary.

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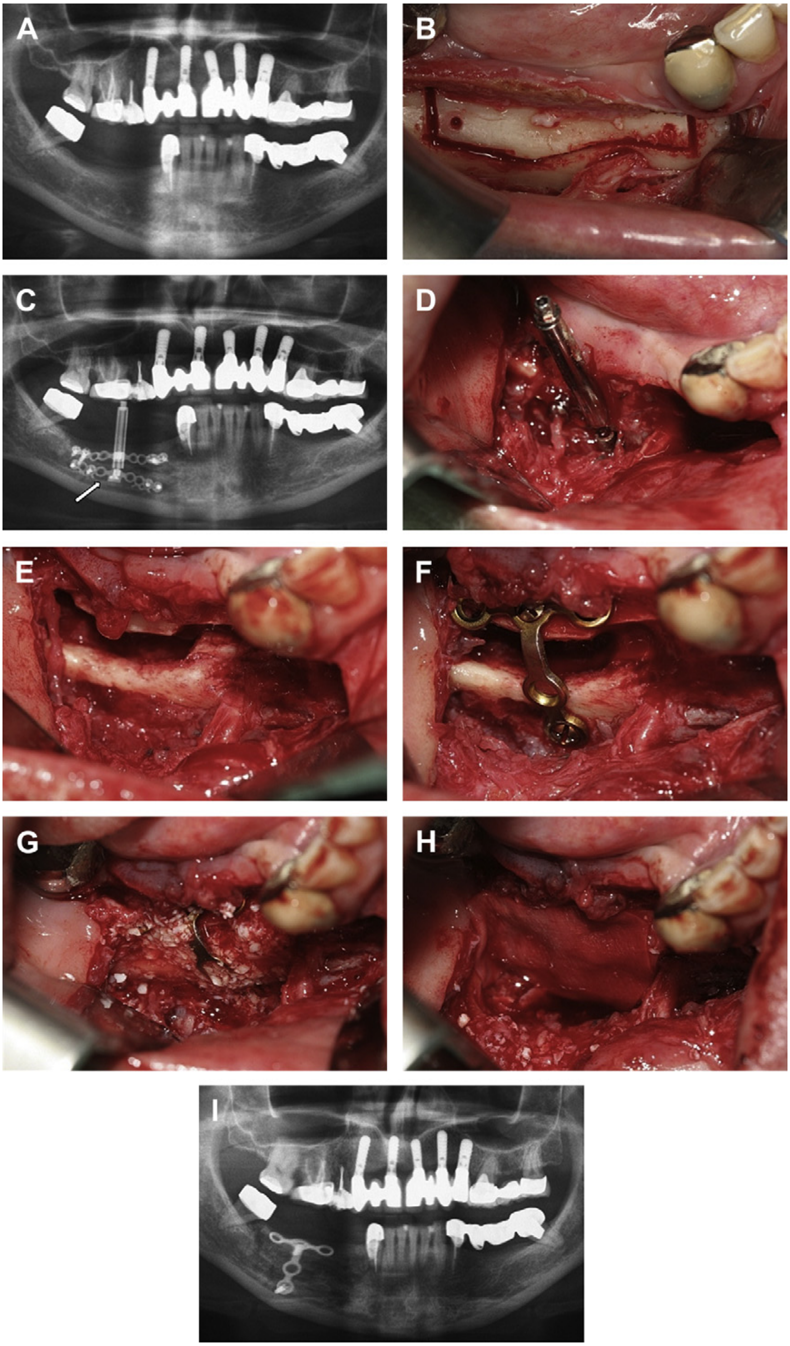

Fig. 8. Fracture of alveolar distractor device treated with bone graft procedure. (*A*) Right mandibular vertical defect. (*B*) Osteotomy. (*C, D*) Panoramic radiograph and clinical picture showing fracture of the alveolar distraction device. (*E*) Distraction gap after removal of device. (*F*) Stabilization of transport segment with miniplates. (*G, H*) Bone graft and membrane in place. (*I*) Radiograph showing vertical bone augmentation.

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Complication Rates of Alveolar Distraction

Despite almost 15 years of clinical practice, growing popularity, and newer technologies, alveolar distraction continues to be a challenging procedure. Alveolar distraction complications have conventionally been classified according to the distraction phases in which they occurred: intraoperative, during distraction, during consolidation, and after distraction. They can also be classified as minor complications or major complications that are more difficult to manage and could jeopardize the distraction procedure. In addition to the common complications of any surgical procedure, such as excessive bleeding, hematoma, infection, and paresthesia, there is a set of specific complications for alveolar distraction. These complications, the possible causes, management, and prevention are listed in **Table 2**.

In more recent years, several articles have focus on the complications of alveolar distraction. These studies have reported a wide array of complication rates, ranging from 36% to 100%.[41,42,66–70] In a comprehensive review of the literature from 1996 to 2008, Saulacic and colleagues[71] studied the complication rate of alveolar distraction. Their results showed an overall complication rate of 30%. The most common complication was insufficient bone formation after the consolidation period (8%), followed by regression of distraction distance (7%), and problems related to the device (6%). Intraoperative complications include bleeding from the floor of the mouth (4%) and temporary paresthesia (4%). During the distraction period, wound dehiscence was found on 1% of the patients. Pain was reported in 1% of the patients, as well as mild soft-tissue resistance. Vector deviation was found in 2%. More severe complications were found during the consolidation period, including a mandibular fracture rate of 2% and problems related to the device in 6% of the cases. They also found that insufficient bone formation and evidence of complications were significantly related to the type of distractor and augmentation rates greater than 0.5 mm daily. The investigators concluded that, although complications in alveolar distraction are frequent, they rarely cause severe problems. They suggested that most of the complications could be related to lack of experience and the learning process.

SUMMARY

Alveolar distraction is a technique in constant evolution. A review of the literature within the past 14 years reveal that there are clear indications for its use, with outcomes similar to and sometimes even more predictable than traditional bone grafting techniques in preparation for implant placement. Although complications exist with alveolar distraction, it seems that most are minor and easy to manage. Appropriate patient selection and a better understanding of the technique are paramount in successful bone regeneration with alveolar distraction osteogenesis.

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Arturo Bilbao
M. Hernández-De Oliveira
Pablo I. Varela-Centelles
J. Seoane

Assessment of dental implant stability in osseodistraction-generated bone: a resonance frequency analysis

Authors' affiliations:
Arturo Bilbao, Service of Maxillofacial Surgery, Santiago de Compostela University Hospital, Santiago de Compostela, Spain
M. Hernández-De Oliveira, Katherine Hospital, Stuttgart, Germany
Pablo I. Varela-Centelles, J. Seoane, Stomatology Department, University of Santiago de Compostela, Santiago de Compostela, Spain

Correspondence to:
Arturo Bilbao
Servicio de Cirugía, Máxilofacial
Hospital Clínico Universitario
Travesía da Choupana s/n
15706 Santiago de Compostela
A Coruña
Spain
Tel.: +34 981 950 000
Fax: +34 981 562 226
e-mails: artubil@terra.com,
arturo.bilbao.alonso@sergas.es

Key words: dental implant, osseodistraction, resonance frequency analysis, stability

Abstract

Objective: To determine the implant stability in osseodistraction-generated (ODG) bone after a 2-month consolidation period, assessed by resonance frequency analysis (RFA).
Material and methods: Twenty healthy, non-smoker female patients received 71 dental implants, 39 placed in native bone and 32 in ODG bone, after an 8-week consolidation period. Primary and secondary stability of the implants was assessed by means of the Osstell® *mentor* device. The average value of six measurements was considered for the statistical analysis at each time point.
Results: The age of the patients who received implants in ODG was not significantly different from that of those receiving implants in pristine bone (48.0 $\pm$ 10.9); [$X = 1.6$; 95% confidence interval (CI) $= -7.7$–10.9].

Although implants placed in both bone types indicated good primary stability, a statistically significant difference in favour of implants placed in pristine bone could be identified in terms of osteogenic distraction (OD) ($X_i - X_j = 3.4$; 95% CI = 1.7–5.8). After a 1.5-month integration period, none of the implants failed, but implant stability still recorded higher values for implants located in the pristine bone ($X_i - X_j = 2.5$; 95% CI = 0.5–4.4).

A positive linear correlation could be established between the implant stability quotient (ISQ) values at implant placement (primary stability) and the post-integration ISQ score (secondary stability) for both bone types, but only 16% of the post-integration ISQ in the ODG bone could be attributed to the primary stability.
Conclusions: Within the limitations of this study, OD bone offers – after a 2-month consolidation period – high primary and secondary stabilities after implant placement.

Osteogenic distraction (OD) is defined as the creation of neoformed bone and adjacent soft tissue after the gradual and controlled displacement of a bone fragment obtained by surgical osteotomy (Cope et al. 1999; Cano et al. 2006a, 2006b). The use of this technique in the maxillofacial area was first reported in 1973, when Snyder et al. (1973) described an experimental application in dog mandibles. Its first clinical indication was published in 1992 for the treatment of patients with hemi facial microsomias using an extraoral distractor (McCarthy et al. 1992).

One of the most relevant applications of this technique in dental implantology is the correction of segmental deficiencies of the alveolar ridge that compromise implant placement either aesthetically or functionally (e.g.: unfavourable crown–implant index) (Urbani et al. 2001; Cano et al. 2006a, 2006b).

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Despite the obvious benefits of this procedure, there still are biological factors like the so-called 'consolidation period' [time between the distraction phase and withdrawal of the distractor (Cano et al. 2006a, 2006b] that may severely compromise the quality of the newly generated bone (Cope et al. 1999). This parameter has only been evaluated in animal models (sheep and dogs) by means of densitometry (Frahadieh et al. 2000), computerised tomography (Smith et al. 1999), conventional radiology (Cope & Samchukov 2001) or histomorphometry and immunohistochemistry (Sawaki et al. 1996; Carls et al. 1997; Cope & Samchukov 2000; Cano et al. 2006a, 2006b) and in humans by analysis of biopsy material taken before to implant placement (Raghoebar et al. 2002; Zaffe et al. 2002).

This background has not produced unequivocal evidence on the optimal time for implant placement in newly distracted bone, and periods ranging between 3 weeks and 3 months have been suggested (Gaggl et al. 2000; Nosaka et al. 2000; Oda et al. 2000); thus, the question on the length of the consolidation period the surgeon should allow still remains. Different histological studies have proved that after an 8-week consolidation period, the bone generated by OD elicits high density (Oda et al. 2000; Cope & Samchukov 2001) and the entire gap is filled with lamellar bone (Carls et al. 1997; Cope & Samchukov 2000; Cano et al. 2006a, 2006b). However, there is a lack of clinically objective information on implant stability after this consolidation period.

The aim of this study has been to determine the implant stability in OD-generated (ODG) bone after a 2-month consolidation period, assessed by resonance frequency analysis (RFA). The secondary objectives were to compare the stability of native bone vs. ODG bone and to study the correlation between primary and secondary implant stabilities in both types of bone.

Patients and methods

A longitudinal intervention study was designed to compare two groups of patients (native bone and osseodistraction-generated bone).

Sample characteristics

Twenty healthy, non-smoker female patients requiring osseointegrated dental rehabilitations entered the study. The mean age of the sample was 48.6 ± 9.9 years (minimum 34 years, maximum 68 years).

After clinical examination and treatment planning, 14 patients were considered suitable for implant placement following the conventional protocols, whereas eight showed severe atrophy of the alveolar ridge that required correction by OD techniques before implant placement was feasible.

The patients in the sample received 71 Straumann® (Institut Straumann AG, Basel, Switzerland) titanium dental implants [average 3.2 ± 1.4 implants per patient (minimum one, maximum six)]. All implants were 10 mm long and with a 4.1 mm RN diameter with an SLA® surface. A total of 39 implants were placed in native bone (25 in the fourth sextant and 16 in the sixth) and 32 in newly ODG bone (12 in the fourth sextant and 20 in the sixth).

Surgical technique

The surgical protocol followed the general surgical protocol for distraction osteogenesis for the posterior mandible, considering the size and width of the transport segment, the position of the lower alveolar nerve and the available inter-occlusal space (Batal & Cottrell 2004).

Local anaesthesia was applied by means of a block technique using a solution of articaine with epinephrine 1 : 100,000 and midazolam sedation. The incision was placed in the attached gingival when possible, and tissue was reflected inferiorly up to a point where a horizontal bony cut could be made for the creation of the transport segment and osteotomy lines were marked. The extraosseous device (Track-Plus; KLS/Martin, Jacksonville, FL, USA) was checked and modulated at this stage. The distractor was withdrawn and the osteotomy was completed using a piezoelectric instrument [Piezosurgery, Mectron S.p.A., Carasco (GE), Italy], under copious irrigation and a chisel. Vertical osteotomies were designed apically convergent to allow displacement of the transported segment and lingually convergent to prevent lingual tipping of the transport segment during distraction. An L-shaped osteotomy was eventually used (a small vertical osteotomy is made in the anterior region of the edentulous ridge, and a long horizontal osteotomy extended from the vertical osteotomy back to the posterior edentulous ridge) (Batal & Cottrell 2004). Once these procedures were completed, the distractor was placed and the absence of interferences was ensured.

The latency period – time from surgery to commencement of distraction – was 5 days. The distraction phase – the period in which traction is applied to the transport segment and the formation of new bone commences – was 7–10 days to obtain an average bony gain of 6 mm. The rate of distraction – distance the bone is lengthened each day – was 0.9 mm/day with a rhythm of distraction – number of distraction events per day – of three movements of 0.3 mm/day. The consolidation period – which follows active distraction and continues until the device is removed – was 8 weeks. After this period, the distractor device was removed and the implants were placed, under local anaesthesia, during the same surgical procedure (Figs 1 and 2).

Implant stability determination

Implant stability was assessed by means of the resonance frequency analysis taking the average value of six measurements performed by the Osstell® *mentor* (Integration Diagnostics AB, Göteborg, Sweden) device directly over the fixation.

The Osstell® *mentor* is a non-destructive system aimed at determining dental implant stability within the oral cavity and the maxillofacial area based on assessment of resonance frequency (FRA) (Meredith et al. 1996). This system includes the use of the Smartpeg® (Integration Diagnostics AB) appliance that is fixed to the dental implant through an integrated screw. The Smartpeg® is activated by a magnetic pulse sent from the probe located on the handheld part of the instrument. The measuring probe integrated in the Osstell® *mentor* device is maintained close to the Smartpeg® but ensuring no contact between them. Then, an acoustic signal confirms the measurement (http://www.osstell.com). The frequency of the resonance, which is the value allocated to the stability of the implant, is calculated from the response signal. The result of the measurement is displayed by the device in implant

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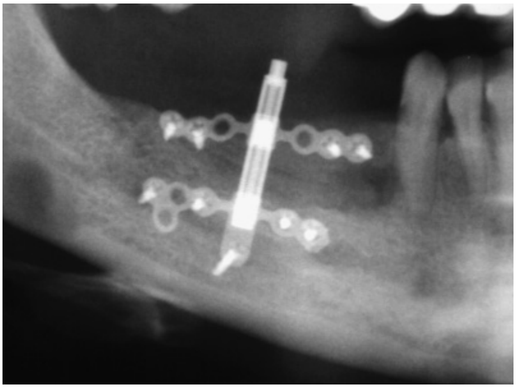

Fig. 1. Distractor in place after a 8 week consolidation period

Fig. 2. Implants placed after removal of the distractor

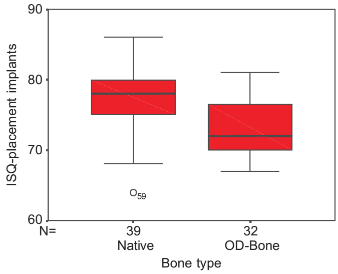

Fig. 3. RFA values for primary stability of the implants

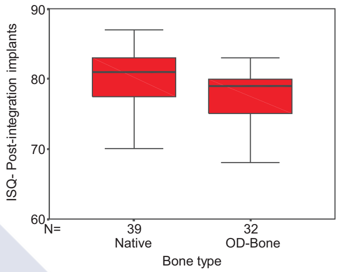

Fig. 4. RFA values for secondary stability of the implants

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stability quotient (ISQ) units that range from 1 to 100 (Aparicio et al. 2006).

Statistical analysis

Statistical analysis was performed by means of an SPSS® + 12 (SPSS Inc., Chicago, IL, USA) statistical package and Epidat 3.1 (Xunta de Galicia, OPS/WHO, Santiago de Compostela, Spain) for Windows. A descriptive statistical analysis was performed using the mean of the distribution as a centralisation parameter and the standard deviation as a spread indicator. The non-parametric Mann–Whitney *U*-test was used for comparison of the means, together with the confidence interval (CI) determined for the difference of the means. The Pearson correlation coefficient was chosen as a measure of linear association between quantitative variables (ISQ) at the time of implant placement (primary stability) and post-integration ISQ (secondary stability). In order to establish the influence of primary stability (predictor variable) on secondary stability (response variable), a linear regression and its coefficient (R^2) were used. The significance level chosen was 5%. Two-sided determination was used in all tests.

Results

The age of the patients who received implants in ODG bone was 49.6 ± 8.4, which was not significantly different from that of the patients receiving implants in pristine bone (48.0 ± 10.9); [$X_i - X_j = 1.6$; 95%CI = 7.7 – 10.9].

The resonance frequency analysis at implant placement in OD bone showed a mean ISQ of 73 ± 4.1, whereas the implants placed in pristine bone yielded a value of 76.8 ± 4.4 ISQ. Although both values indicate good primary stability, a statistically significant difference in favour of implant placed in pristine bone could be identified in terms of OD ($X_i - X_j = 3.4$; 95% CI = 1.7–5.8) (Fig. 3).

After a 1.5-month integration period, none of the implants failed, and the mean ISQ of OD bone was 77.2 ± 4.0 for 79.7 ± 4.2 of the implants placed in pristine bone. Again, implant stability was higher for implants located in pristine bone ($X_i - X_j = 2.5$; 95%CI = 0.5–4.4) (Fig. 4).

A positive linear correlation could be established between the ISQ values at implant placement (primary stability) and post-integration ISQ score (secondary stability) both for the OD bone ($r_{xy} = 0.4$; $P = 0.02$) and for the pristine bone ($r_{xy} = 0.61$; $P = 0.000$). However, it is worth noting that the regression line for native bone had a determination coefficient (R^2) of 0.37, which indicates that 37% of the variation of the post-integration ISQ can be explained by the initial ISQ (primary stability). In OD-bone, this coefficient was 0.16; thus, only 16% of the

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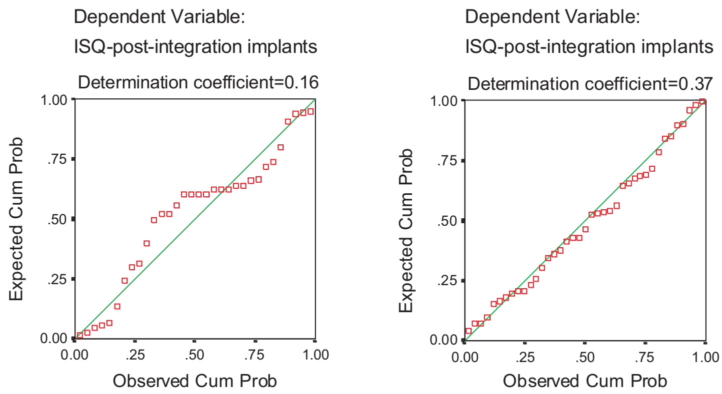

Fig. 5. Linear regression adjustment for ISQ values in ODG (left) and native (right) bones

post-integration ISQ could be attributed to primary stability (Fig. 5).

Discussion

Distraction osteogenesis can efficiently augment bone vertically (Esposito et al. 2003). This technique is highly predictable, with reported success rates from 96% to 100% (Chiapasco et al. 2001, 2006). Nowadays, studies on alveolar distraction remain at the experimental stage and are scarce in the scientific literature (Cano et al. 2006a, 2006b).

The implant survival rate in OD-bone appears to be comparable to that of non-distracted bone (Block et al. 1998, 2000; Jensen et al. 2000; Rachmiel et al. 2001; Chiapasco et al. 2006), with percentages of 90.4–100% (Chiapasco et al. 2006). However, there is not enough scientific evidence to allow for individualised protocols for implant insertion that take into account biological or biomechanical factors involved in OD, like consolidation time, distractor design, age, gender, anatomical site, bone density or the general status of the patient (Cope et al. 1999; Cano et al. 2006a, 2006b).

Despite accurate knowledge of what levels of primary stability can be obtained in different jawbone regions and what particular factors influence primary stability (Ostman et al. 2006), this factor still impairs implant survival (Stanford 2005) and it is largely a mechanical parameter determined by bone density, implant design and surgical technique (Glauser et al. 2004). In ODG bone, some other factors should be added to this list: gender – greater stability in males (Zix et al. 2005; Ostman et al. 2006) – and anatomical site – higher stability in the mandible (Ersanli et al. 2005; Ostman et al. 2006).

The RFA is a non-destructive method extensively used in clinical research to monitor implant stability due to its high reproducibility (Aparicio et al. 2006). RFA has also been used to assess the osseointegration period, immediate load feasibility and in follow-up studies aimed at predicting implant failure (Huang et al. 2002; Ersanli et al. 2005). RFA values/ISQ levels correlate positively with bone quality (Bischof et al. 2004; Balshi et al. 2005; Ostman et al. 2006) and are affected by factors such as bone tissue features, implant sink depth, diameter or type of surface (Aparicio et al. 2006) and have to be calibrated for each implant system separately (Ersanli et al. 2005).

In order to control the confounding factors that may influence the determination of primary stability of the implants, restrictive inclusion criteria were established that reduced the sample to female patients with posterior mandibular implants. The cornerstones for increasing accuracy at implant stability determination were the use of a high-precision automatic device (Ostell® *mentor*) with periodic calibrations and repeated measurements to reduce random errors. However, and due to the homogeneity of the sample, generalisation of the results reported in this study to other clinical situations should be performed with caution.

Metalloproteinase analysis in animal models (sheep) showed that distracted bone was remodelled until 9 months after distraction. After this period, OD-bone followed a stable remodelling pattern similar to that of non-distracted bone (Marucci et al. 2001). However, there is a generalised trend towards diminishing this consolidation period to avoid infectious complications, but it is mandatory to keep the distractor in place long enough to obtain a tissue able to withstand the biomechanical implications of implant placement (Cano et al. 2006a, 2006b). A 3-week consolidation period offers an immature bone that starts to form columns from the borders of the distracted area (Nosaka et al. 2000). After a 3-month consolidation period, the cumulative success rate of dental implants was 100% in human models (Chiapasco et al. 2001, 2006; Rachmiel et al. 2001).

Histological studies performed in humans have proved the presence of bone trabecula parallel to the distraction vector and support the criterion that an 8-week consolidation period is enough for implant placement (Raghoebar et al. 2002; Zaffe et al. 2002; Cano et al. 2006). In this series, with the same consolidation period, high primary stability was obtained only slightly lower than that achieved in native bone. ISQ values obtained both for native and for OD bone are well within the limits considered suitable for immediate implant loading. This consolidation has provided maintenance of the regenerated bone

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without collapse or fracture of the area. Our results agree with those of Rachmiel, who, with an identical consolidation period and a 6–20-month follow-up period after OD, reported a single failure (out of 22 implants) due to improper distracted segment stability (Jensen et al. 2000).

Previous reports on native bone using RFA have showed a decrease in bone–implant stability in the first month after implant placement (Balshi et al. 2005), followed by increases in stability in the second and third months, suggesting a process of adaptative bone remodelling around the implant (Balshi et al. 2005; Ersanli et al. 2005). In this series, after a 1.5-month osseointegration period, the secondary stability scores were high, with ISQ values slightly higher than those elicited at implant placement. There also seems to exist a better positive linear association in native bone between primary and secondary implant stability.

It is concluded that, within the limitations of this study, OD bone offers – after a 2-month consolidation period – high primary and secondary stabilities after implant placement.

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Lateral transport osteogenesis in maxillofacial oncology patients for rehabilitation with dental implants: a retrospective case series

Arturo Bilbao-Alonso [1], José-María García-Rielo [1], Pablo Varela-Centelles [2], Juan Seoane [2]

[1] Service of Oral and Maxillofacial Surgery. Santiago de Compostela University Hospital. Santiago de Compostela (A Coruña). Spain
[2] Stomatology Department. School of Medicine and Dentistry. University of Santiago de Compostela. Santiago de Compostela (A Coruña). Spain

Correspondence:
Cantón Grande 5, Apt. 1º E
15003 A Coruña. Spain
juanmanuel.seoane@ usc.es

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Abstract
Objectives: To report on the use of lateral transport osteogenesis in cancer patients after maxillo/mandibular resections and on the implant survival rate in the generated bone
Material and Methods: Four patients treated using lateral transport osteogenesis entered this descriptive study and were retrospectively studied (mean age 55; range 41-62).
Results: Reconstruction of segmentary defects after surgical and radiological cancer treatment on maxilla and mandible was achieved. No relevant intra- or post-operative complications occurred. No differences on implant survival were observed between patients who had received radiotherapy and those who had not.
Conclusions: This approach can be considered a recommendable reconstructive option after oral cancer treatment –including radiotherapy- particularly for high-surgical-risk, collaborative patients.

Key words: *Distraction osteogenesis, oral cancer, radiotherapy, reconstruction, dental implants.*

Introduction
Many maxillofacial tumours are diagnosed at advanced stages with frequent mandible/maxillary involvement, resulting in marginal or segmental resection with adjuvant radiotherapy. The vascularised free-osseous flap (VFOF) is the current gold standard for reconstruction in these situations (1) although this procedure is far from ideal for patients with increased surgical risk and for those requiring an adequate soft tissue quality before implant insertion, as VFOF results in a too thick overlying soft tissue without peri-implant attached gingival (1,2).
Osteogenic distraction procedures, like transport-disc-distraction-osteogenesis (TDDO), may solve these shortcomings as no statistically significant differences could be found between autogenous bone and distracted bone sites in terms of stability and implant survival rate (3-6). The main limitation of such techniques in these

situations would come from the effects of radiotherapy, applied either before or after distraction, on the regenerated bone (7,8).
This paper reports on the use of lateral transport osteogenesis in cancer patients who have undergone maxillo/mandibular resections and on the implant survival rate in the generated bone.

Material and Methods

Four patients with segmental defects after oncological resection were descriptively studied (mean age 55; range 41 to 62) (Table 1). The lateral bone transport technique was used to reconstruct the maxillary and mandibular bone defects in all cases: periosteum over the designed transport disk was preserved during the procedure to ensure vascularity, and the ostectomy was performed by means of a piezoelectric device (Piezosurgery System; Mectron Medical Technology, Carasco, Genoa, Italy) 7 to 15 mm away from the defect to create the transport disk. The MODUS modular distractor (Medaris AG, Basel, Switzerland) was used in the maxilla and the KLS system (Martin intraoral distractor, USA) in the mandible (Figs. 1,2) . The devices were not activated until the 5th or 6th day (latency period). The chosen distraction/contraction protocol progressed at a distraction rate of 0.75 mm a day for three days to contract another 0.75 mm on the forth day -in order to avoid excessive tension on the soft tissues- and continued until the device's distal stump was reached. A consolidation period of 8 to 12 weeks was allowed, and the

Fig. 1. Patient number 3 after lateral transport osteogenesis with adequate gingival tissues for implant placement.

Table 1. Patients' clinical and pathological features.

Patient ID/ Gender/ Age	Primary diagnosis	Defect location	Local teatment	Neck treatment	Radiotherapy	Secondary dagnosis
1/male/61	SCC	Maxilla (right)	Maxillectomy and reconstruction by miofascial temporal flap.	Ipsilateral radical neck dissection.	Yes (60GY)	Neck recurrence alter 12 months
2/female/41	Chondrosarcoma	Maxilla + malar (right)	Maxillectomy and reconstruction by scapular flap (failed). 2nd reconstruction by radial antebrachial flap.	Ipsilateral neck dissection	Yes (60GY)	TMJ ankylosis post-radiotherapy
3/male/56	SCC	Maxilla (left, rear)	Maxillectomy and reconstruction by Bichat pad flap.	Ipsilateral neck dissection	No	Neck metastases
4/male/62	SCC	Mandible (left)	Resection and primary closure	Ipsilateral neck dissection	No	-

TMJ: Temporomandibular joint; SCC: squamous cell carcinoma.

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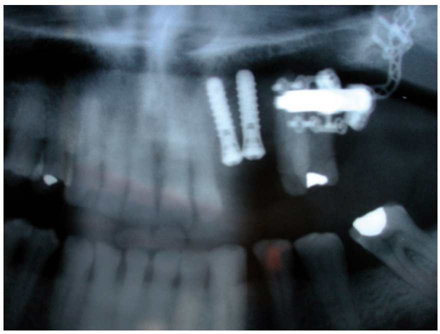

Fig. 2. Detail from orthopantomograph image showing implants placed in newly generated bone before osteodistractor removal.

dental implants were placed (4.1 mm diameter, 12 mm long, Standard Plus, with a SLA® surface Straumann AG, Waldenburg, Switzerland). Patients were followed for periods ranging from 3 to 9 years, under a protocol that included clinical and radiographic assessment with intraoral radiographs at the time of implant placement and at 1, 3, 6 and 12 months and yearly thereafter.
The variables considered in the study included an assessment of surgical intra and post-operative morbidity, defect location and size, transport disc length, length of the distracted bone, consolidation period and survival rates.

Results

The results are summarized in table 2. The use of lateral transport osteogenesis techniques in these series has permitted the reconstruction of segmentary defects between 30 to 55 mm length, after surgical and radiological maxillofacial cancer treatment. None of the cases showed relevant intra- or post-operative complications. No differences in terms of implant survival were observed between the two patients who had received radiotherapy and those who had not. In both situations, a 100% implant survival rates could be achieved for the implants placed in TDDD generated bone.

Table 2. Lateral transport osteogenesis description.

Patient	Defect location	Defect length (mm)	Transport disk length (mm)	Distracted Bone lengthening (mm)	Consolidation period (wk)	No. Implants (survival %)	Complications	Follow-up (yr)
1	Maxilla (right)	40	7	22	10	4 (100)	No	9
2	Maxilla (right)	35	15	15	8	2 (100% in distracted bone)	1 pterigoid implant lost (native bone)	5
3	Maxilla (left)	30	12	15	10	2 (100)	No	3
4	Mandible (left)	55	10	44	12	3 (100)	No	5

wk: week; yr: year; No: number

Discussion

TDDO has been recently recognised as a valuable alternative for mandibular reconstruction after surgical resection and radiotherapy, producing functional bone similar to residual bone (3,8). Short case series, mostly reporting on mandible, show success rates close to 83% (5), but the information available about this procedure for maxillary reconstruction and the influence of radiotherapy on its results is limited. This may well be due to the difficulty to obtain an adequate morphology on curved segments, which could make a 2-phase distraction mandatory. Moreover, implants placed in maxilla after radiotherapy have proved a poor survival rate (59%), (9) although studies on this situation are so scarce that no definitive conclusions can be drawn.
In this series, all 6 implants inserted in patients who had received maxillary radiotherapy (patients 1 & 2) elicited a 100% five-year survival rate, despite the fact that the described procedures are different from more conservative protocols (0.5 mm a day and/or twice long consolidation period) reported in the literature (10).

It is concluded that, with the inherent limitations to such a small case series, TDDO may well be considered a recommendable reconstructive option, both for maxilla and mandible, in patients having undergone oral cancer therapy –including radiotherapy- particularly for high-surgical-risk, collaborative patients. However, controlled randomized clinical trials supporting this therapeutic approach are needed to endorse this technique.

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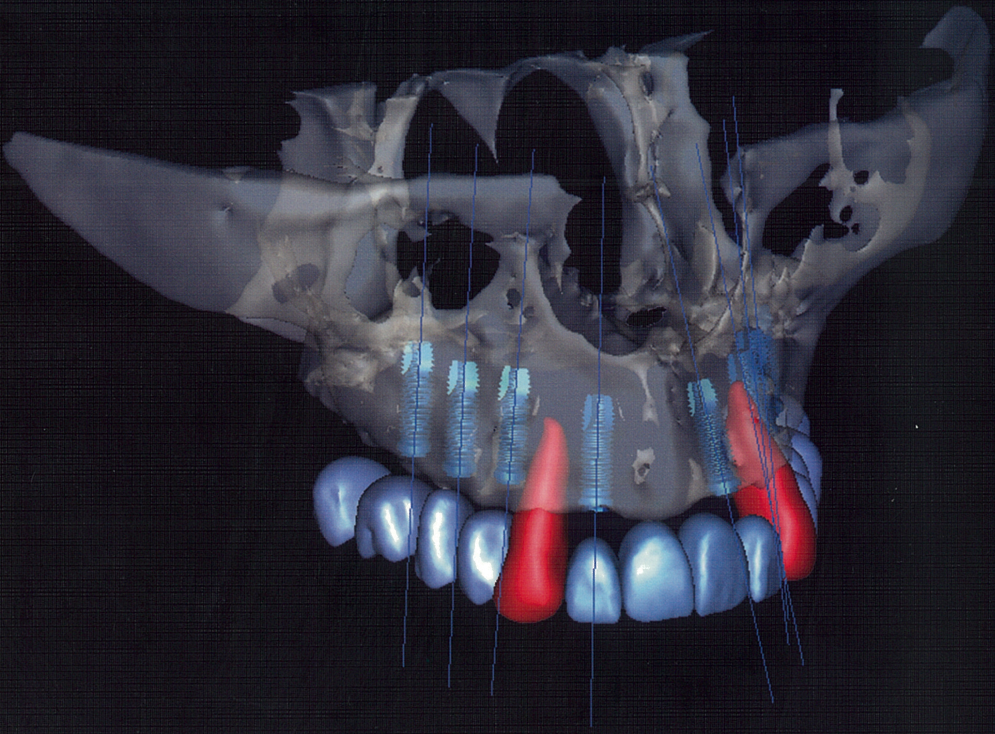
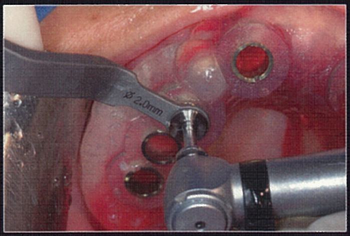
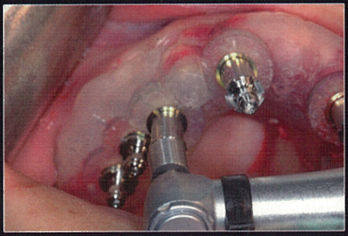
Planificación 3D y Cirugía Guiada en Implantología Oral

José Carlos Moreno Vázquez







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Ronda del Caballero de la Mancha, 135 - 28034 Madrid, España
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tecva@andinanet.net

Ecuador:
Ing. Marco Vinicio Segura Silva
Laureles 708 y Av. Las Aguas "Urdesa Central"
Guayaquil-Ecuador
Telf.: +59342-389724
Mail: amodsaec@yahoo.com;
m_romero_a@yahoo.com

Ripano Francia:
Teléfono (+33) 450 940 336
prperez@wanadoo.fr

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Corp. Educativa Guatemala
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Telfs: (+502) 2232-7850
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Ripano, México:
Sr. Edgar Molina
Blvd. Adolfo Lopez Mateos Núm. 1384 1er piso Col. Santa María Nonoalco.
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marketing@orthoportugal.com

República Dominicana:
Manolito Dental S.A.
Sr. Manuel Valentín
Presidente Hipólito Irigoyen nº 1ª
Zona Universitaria - Santo Domingo
Telf. (+809) 533 2532
manolitodental@codetel.net.do

Uruguay:
Editorial Daniel Barreiro.
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Tel-Fax: (598-2) 622-1874.
Cel: 099-624-972.
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Ripano, Venezuela:
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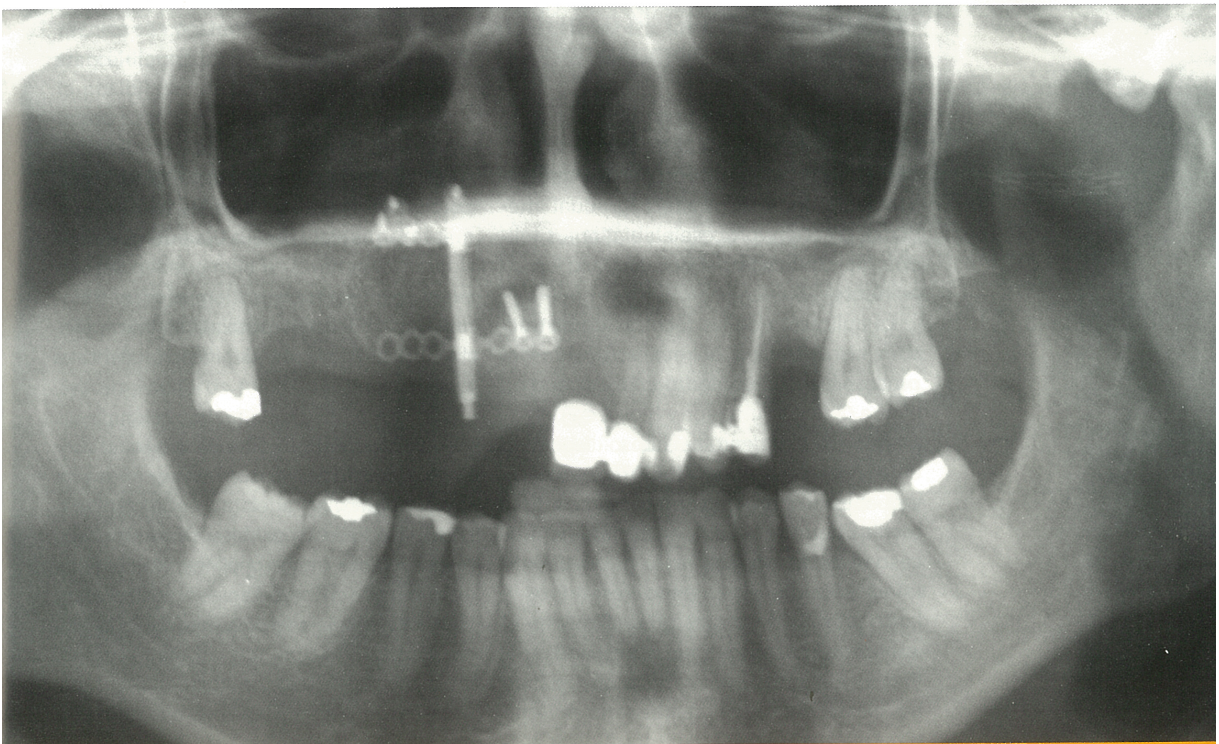
Capítulo I.8

Implantología guiada y distracción alveolar

Arturo Bilbao Alonso
Jose María García Rielo



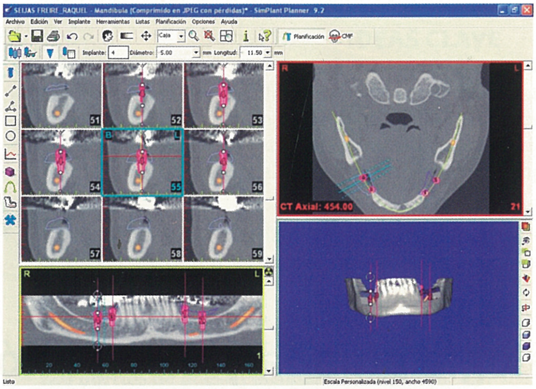


Figura 1. Planificación de implantes y segmento a distraer.

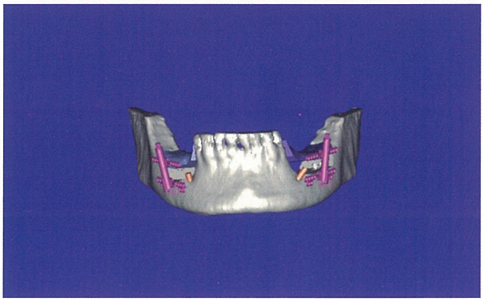


Figura 2. Simulación de la distracción.

INTRODUCCIÓN

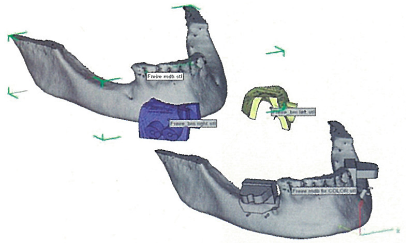
La distracción es un proceso biológico de formación ósea que acontece entre las superficies de segmentos de hueso vital que son separados de manera gradual mediante tracción, proceso en el que los tejidos blandos acompañan al hueso en su aumento.

La aplicación de las técnicas de distracción histogénica a la reconstrucción del proceso alveolar comenzó en 1996, año en el que Chin en humanos y Block en perros describen el aumento del hueso disponible en el reborde alveolar utilizando técnicas ya habituales en el esqueleto facial. Esta técnica permite la reconstrucción del proceso alveolar eliminando la necesidad de injertos óseos obteniendo resultados a largo plazo incluso más predecibles en el aumento vertical que los observados utilizando otras técnicas de forma que, si bien no existe evidencia científica suficiente para afirmar que sea superior a otras técnicas, se considera que para defectos de 6 a 10 mm en el sentido vertical (tipo II según la clasificación de Jensen y Block) puede ser el tratamiento ideal, debiendo considerar el remanente óseo disponible para defectos mayores.

Tras el boom inicial de la técnica se observaron múltiples contratiempos que llevaron a la descripción de series con alarmantes porcentajes de complicaciones. Afortunadamente la mayoría de ellas pueden ser consideradas menores, si bien pueden llegar a suponer un serio contratiempo en el tratamiento, y muchas se podrían minimizar mediante una adecuada planificación del caso en su conjunto.

La generalización de la utilización de los estudios tridimensionales de imagen y confección de modelos estereolitográficos ha supuesto un paso adelante en la planificación inicial del caso, si bien como veremos más adelante, las especiales condiciones anatómicas del hueso que estamos tratando hacen difícil una correcta predicción de los resultados.

Ya en el año 2000 Gaagl presenta un estudio realizado sobre nueve pacientes en los que la planificación para la colocación de implantes distractores se realiza previo estudio de modelos confeccionados a partir de estudios de tomografía axial computarizada en tres dimensiones. Esta



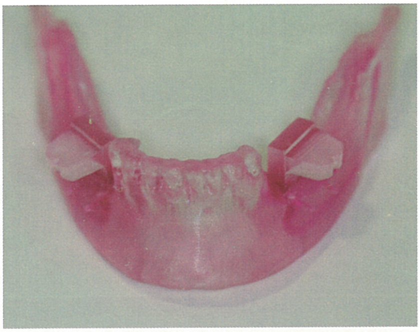
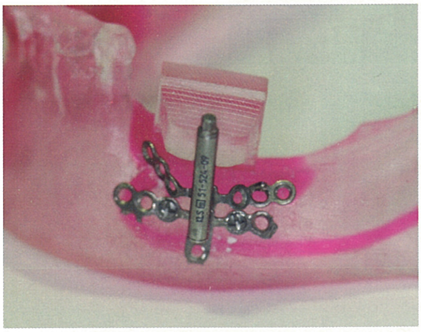


Figura 3. Planificación del segment a distraer y posición de tornillos iniciales.

Figura 4. Modelo estereolitográfico que registra el vector planificado.



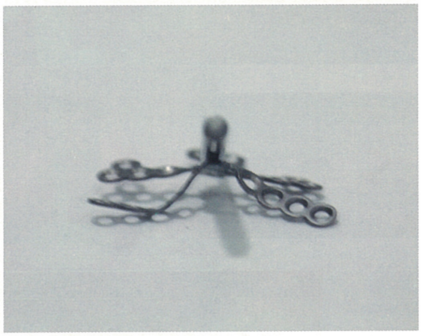


Figura 5. Modelado del distractor sobre el modelo estereolitográfico donde va marcado el vector y la posición de los tornillos.

Figura 6. Distractor modelado y listo para esterilizar.

técnica se consideraba el standard en distracción craneofacial, si bien ya se sugería la posibilidad de utilizar la cirugía virtual como principal herramienta de planificación. No se cita el control del vector de distracción en el postoperatorio, punto que se ha mostrado de vital importancia en toda la literatura aparecida posteriormente.

El trabajo de Kanno muestra la planificación de la colocación de distractores bidireccionales (V2-Alveolar Distraction System;Medartis AG, Basel, Switzerland) mediante el software SimPlant CMF/OS Pro (Materialise, Leuven, Belgium) y cómo a pesar de realizar la máxima corrección posible en todos los casos, existe una importante desviación entre el resultado final y el desplazamiento buscado con el dispositivo. Esto se debe a la tensión ejercida por los tejidos blandos, especialmente la fibromucosa palatina y la musculatura circundante, lo que ha llevado a algunos autores a propugnar el abordaje palatino en casos de distracción en la región de la premaxila. Este fenómeno de variación y pérdida del vector es más frecuente en el caso de la utilización de distractores de tipo intraóseo.

UTILIDAD DE LA CIRUGÍA GUIADA EN DISTRACCIÓN ALVEOLAR

La planificación 3D asistida por ordenador en casos de distracción alveolar permite:

- Estudio del defecto óseo.
- Provisión de un canal de comunicación entre profesionales de gran exactitud.
- Planificación de los implantes de acuerdo con la filosofía arriba-abajo. (Fig. 1).
- Diseño de la osteotomía (tamaño y forma) (Fig. 2).
- Comprobación de ausencia de contactos.
- Elección del dispositivo a colocar.
- Determinación de la situación de los tornillos (Fig. 3).
- Comprobación de ausencia de colisiones anatómicas o invasión de estructuras adyacentes.
- Planificación del vector inicial de distracción (Fig. 4).
- Conformación del distractor (forma, tamaño, angulación) para su esterilización previa a la cirugía (Figs. 5 y 6).

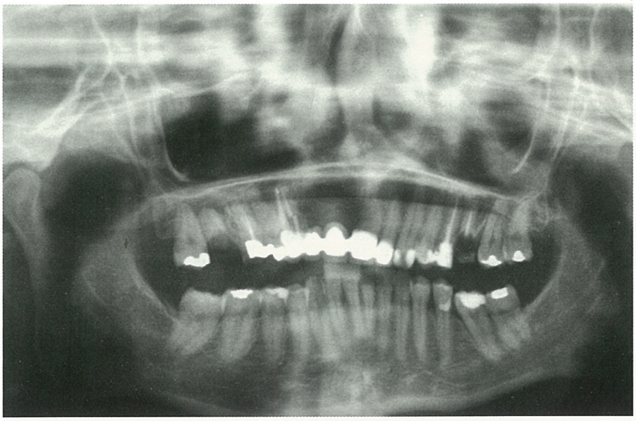


Figura 7. Ortopantomografía inicial

Figura 8. Planificación utilizando Simplant CMF-OS.

Figura 9. Planificación utilizando Simplant CMF-OS.

Figura 10. Planificación utilizando Simplant CMF-OS.

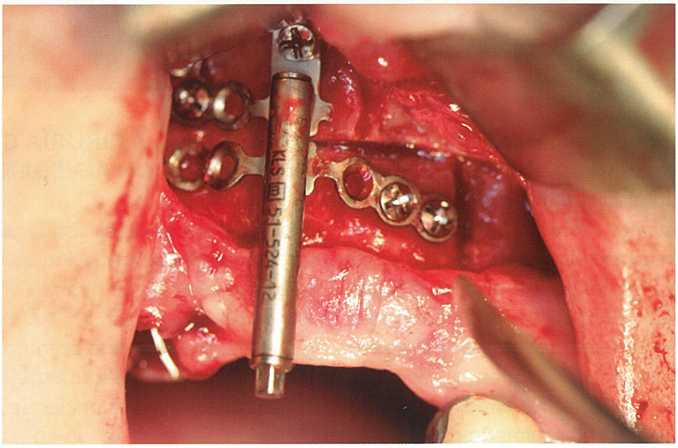


Figura 11. Distractor colocado.

- Cálculo del aumento de hueso necesario considerando una sobre-corrección del defecto , que según algunos autores puede llegar a ser del 25%.
- Aplicación de técnicas de control postoperatorio del vector (dirección, longitud, apoyo en mesial y distal, utilización de elementos de prótesis y/o ortodoncia).

CASO CLÍNICO. CORRECCIÓN DE DEFECTO POSTRAUMÁTICO

Paciente mujer de 32 años que sufrió 15 años antes traumatismo con fractura de maxilar superior, mandíbula y proceso alveolar, tratada con fijación Intermaxilar con alambres. Posteriormente fue sometida a injerto antólogo que fracasó por exposición siendo portadora de prótesis fija dentosoportada.

En el momento en el que acude a la consulta presenta defecto alveolar en región de incisivo central-canino superior derechos, con desviación de línea media (Fig. 7) y plano oclusal inclinado. La paciente no desea corrección ortognática de dicha desviación y rechaza la colocación de nuevos injertos.

Se planifica con el sistema SimPlant OMS osteotomía en región de defecto (Figs. 8, 9 y 10) y se lleva a cabo distracción de 8 mm con un distractor Track Plus (KLS Martin, Tuttinger, Germany) (Figs. 11 y 12) Se realizan extracciones de piezas con caries y procesos apicales y, tras 12 semanas de consolidación del callo de distracción, (Figs. 13, 14, 15 y 16) se colocan 4 implantes de 4,1 x 12 mm esthetic plus sistema ITI® (Straumann AG, Basel, Switzerland) con técnica sumergida, trasponiendo tejido conectivo palatino para mejorar el grosor gingival en todo el frente anterior (Fig. 17). Tres meses más tarde se descubren los implantes con bisturí circular (Fig 18) y se confecciona prótesis fija (Dr. Pazos Carbón) (Figs. 19 y 20).

Es de reseñar que la exposición del dispositivo durante la fase de consolidación (Fig 14) no supuso ningún inconveniente para la continuación del tratamiento.

Posteriormente se infiltra el labio con material reabsorbible a largo plazo Hydrafill® grado III para recuperar volumen en las zonas deficitarias por la cicatriz del traumatismo inicial (Fig. 21).

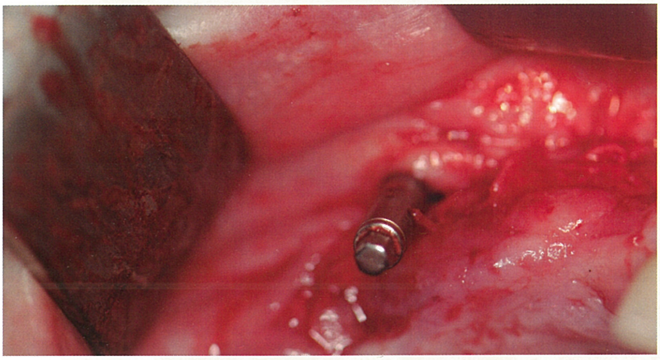


Figura. 12. Vector de distracción.

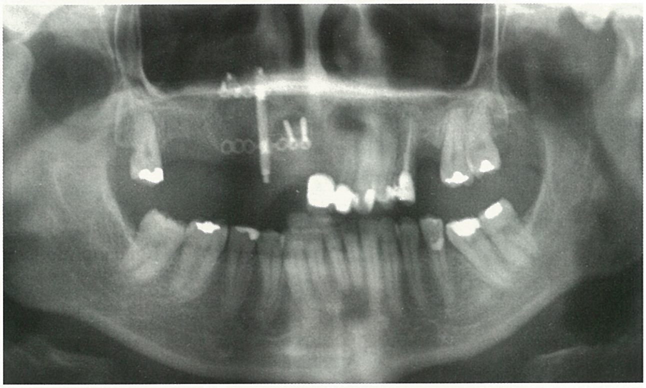


Figura 13. Control radiológico al final de la distracción.

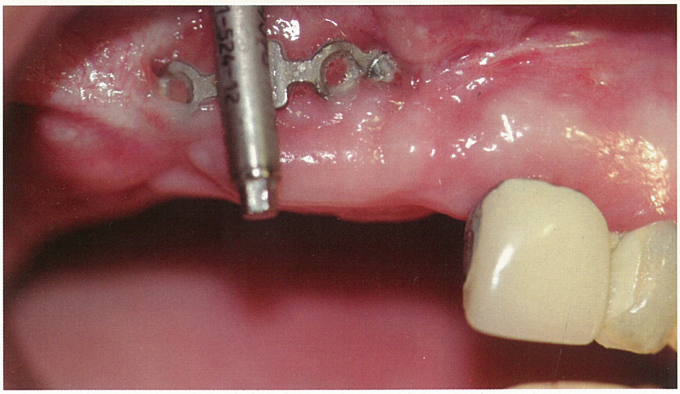


Figura 14. Imagen clínica al final de la consolidación.

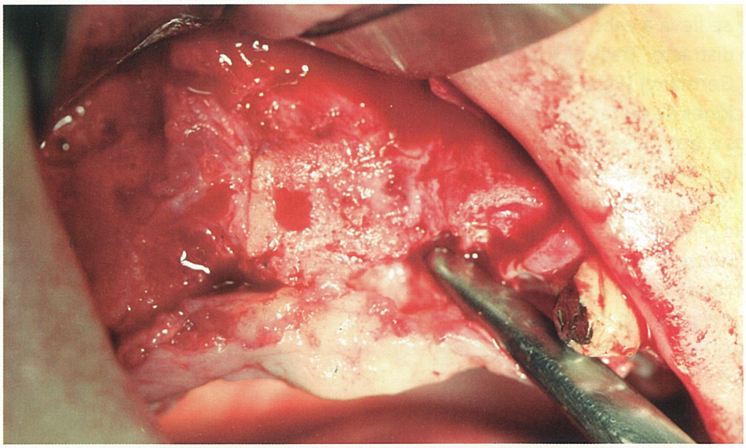


Figura 15. Reentrada para la colocación de implantes.

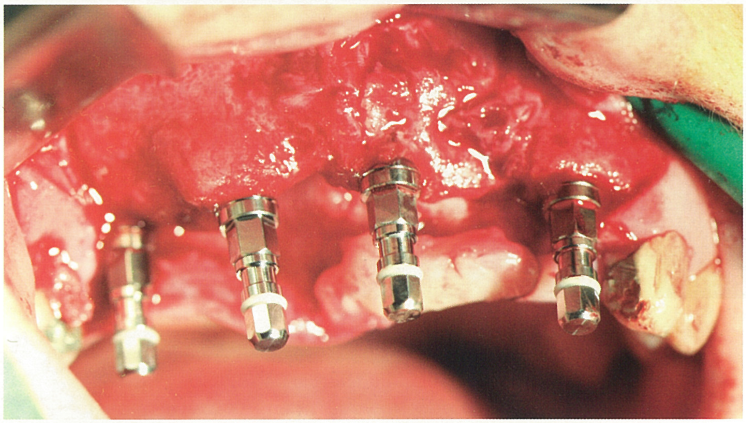


Figura 16. Colocación de 4 implantes osteointegrados.

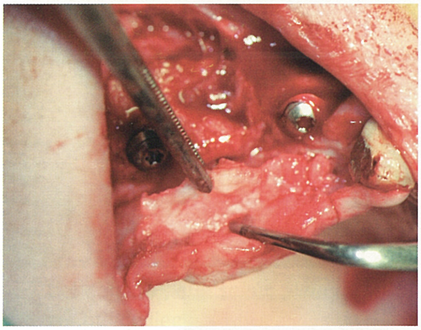


Figura 17. Colgajo pediculado de tejido conectivo palatino.

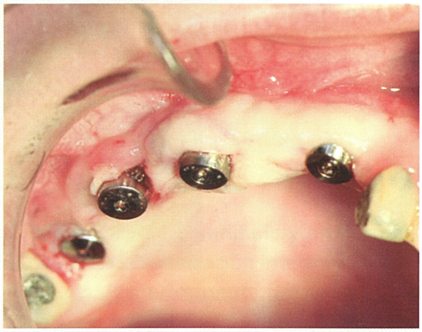


Figura 18. Segunda fase quirúrgica.

Figura 19. Prótesis fija definitiva.

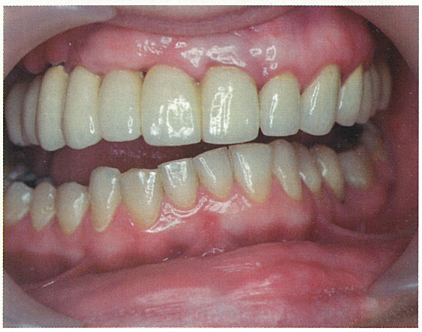


Figura 20. Prótesis fija definitiva.

Fig.21 Estado tras relleno labial

IDEAS CLAVE

- La distracción alveolar ha pasado por un periodo de entusiasmo inicial seguido de un periodo de alarma por la aparición de numerosas complicaciones.
- Muchas complicaciones se podrían minimizar mediante una adecuada planificación del caso en su conjunto.
- La planificación 3D es una herramienta ideal en la distracción alveolar porque permite estudiar adecuadamente la morfología de los fragmentos, diseñar la línea de osteotomía y determinar la mejor dirección del vector de distracción.
- La fabricación de modelos estereolitográficos preoperatorios permite modelar el distractor antes de la intervención, habiendo previamente decidido la mejor posición de los tornillos.
- La tracción ejercida por los tejidos blandos impide en ocasiones mantener el vector de distracción planificado preoperatoriamente.
- La planificación simultánea de los implantes que se colocarán después del periodo de consolidación permite calcular la sobre-corrección necesaria.

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